

# **EPA Jacket 65331-8**

# DATA PACKAGE BEAN SHEET

Date: 21-Feb-2013

Page 1 of 2

Decision #: 475004

DP #: (409349)

PRIA

Parent DP #:

Submission #: 930715

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 65331-8 - TRADENAME FOR DOGS

Company: 65331 - Merial Limited

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Richard Gebken RGEKEN

Sent Date:

PRIA Due Date: 16-May-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R340) AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LAE

Ingredients: t09701, Permethrin(44.88%)

t29121, Fipronil(6.01%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 21-Feb-2013

Due Back:

DP Ingredient: t09701, Permethrin

t29121, Fipronil

DP Title: Acute Toxicity data

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 16-Apr-2013

Team Name: Tox

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

The registrant has been challenged with a petition to deny from the me-too registrant (Virbac) for citing exclusive use data. Merial is providing information to remedy the data deficiencies in their current application since Virbac would not provide permission to utilize their data. Please review this package to determine if their Acute Toxicity data is valid for use.

Thanks

Richard Gebken

\* Make sure  
Byron does 20

DP#: (409349)

\*\*\* Studies Sent for Review \*\*\*

Decision#: (475004)

MRID	MRID Status	Citation Reference	Guideline	MRID Status
49027300		Merial Limited (2013) Submission of Efficacy, Safety and Toxicity Data in Support of the Registration of Certishield for Dogs. Transmittal of 6 Studies.		Pass (25-Jan-2013)
49027302		Vasquez, R. (2012) ML-3, 141,301: Acute Oral Toxicity Study in the Rat: Final Rat. Project Number: 0406RM52/005, PR/D/0254801. Unpublished study prepared by Calvert Preclinical Services, Inc. 55p.	870.1100/Acute Oral Toxicity	Pass (25-Jan-2013)
49027303		Vasquez, R. (2012) ML-3, 141,301: Primary Dermal Irritation Study in Rabbits: Final Report. Project Number: 0420LM52/005, PR/D/02550/0255001. Unpublished study prepared by Calvert Preclinical Services, Inc. 64p.	870.2500/Acute dermal irritation	Pass (25-Jan-2013)
49027304		Vasquez, R. (2012) ML-3, 141,301: Primary Eye Irritation Study in Rabbits: Final Report. Project Number: 0421LM52/004, PR/D/02551/0255101. Unpublished study prepared by Calvert Preclinical Services, Inc. 67p.	870.2400/Acute eye irritation	Pass (25-Jan-2013)
49027305		Vasquez, R. (2012) ML-3, 141,301: Acute Dermal Toxicity Study in Rats: Final Report. Project Number: 0422RM52/005, PR/D/02549/0254901. Unpublished study prepared by Calvert Preclinical Services, Inc. 58p.	870.1200/Acute dermal toxicity	Pass (25-Jan-2013)
49027306		Vasquez, R. (2012) Delayed Contact Hypersensitivity in Hartley Guinea Pigs (Buehler Method) with ML-3, 141,301: Final Report. Project Number: 0424GM52/003, PR/D/02724/0272401. Unpublished study prepared by Calvert Preclinical Services, Inc. 62p.	870.2600/Skin sensitization	Pass (25-Jan-2013)



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg.  
Number:  
65331-8

Date of Issuance:  
05/11/2012

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Tradename for Dogs

Name and Address of Registrant (include ZIP Code):

Merial Ltd.  
3239 Satellite Blvd.  
Duluth, GA 30096

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec 3(c)(7)(A), contingent on the following:

1. Make the following labeling changes before releasing the product for shipment:
  - a. Revise the EPA Registration Number to read: "EPA Registration No. 65331-8".

Signature of Approving Official:

See page 4

Richard Gebken,  
Product Manager (RM 10)  
Insecticide Branch  
Registration Division (MC 7505P)

Date:

May 11, 2012

- b. Delete the marketing claim "*Available [through Veterinarians] [from a licensed veterinary professional] [from a licensed veterinarian]*"
  - c. State the "full net contents for multiple packages".
  - d. Remove/delete the claim "*Kills flea eggs and larvae*" throughout label.
  - e. Change "mites" to "*Sarcoptic mange mites*"
  - f. State the lower weight limit on blister pack, etc.
  - g. Delete the statement "*The killing of fleas and ticks is important in the prevention of disease transmission by these parasites*"
  - h. Under the subtitle "*Alternate marketing text for carton or insert*" (pgs 13 – 18), see mark-up corrections on the label and revise accordingly.
2. This registration is time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration (NOR). The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.

3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
4. Submit the following data within the timeframe described below:
- Within sixteen (16) months of the date on this NOR - Guideline Studies OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).*
- Within twelve (12) months of the date on this NOR - Guideline Study OPPTS 830.1650 (Description of the formulation process).*
5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2012.

The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
- Product name (brand name)
- Lot #
- Where purchased: internet, store, Veterinarian
- Active Ingredient(s)
- Weight range for product

Date on which incident occurred. (mm/dd/yyyy)  
 State in which the incident occurred. (standard 2 letter abbreviation)  
 Registrant case #

Species: dog, cat, other (specify)  
 Breed: (as reported by pet owner)  
 Age: months or years  
 Sex: M, F, or neutered  
 Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other  
 Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted with separate column for each sign, using standard terminology  
 Time to Onset: (hours, days)  
 Treated by veterinarian: yes or no  
 First time product used: yes or no  
 Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)  
 Any known precondition  
 EPA Severity Code: death, major, moderate, minor  
 Outcome: died, recovered, still treated, unknown

6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
  - a. All minor dermal and ocular irritation reports.
  - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
  - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
  - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
  - h. Table showing number of incidents for each dog breed.
  - i. Table showing number of incidents in dogs for each clinical sign.
  - j. Table showing number of incidents in dogs for each organ system.
  - k. Report aggregate incidents, but do not combine moderate and minor incidents.

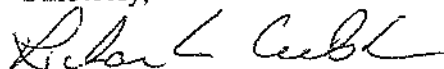
7. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for re-registration (registration review) of your product under FIFRA section 4.

This NOR was issued with the understanding that you will ensure that the labeling for this product (a) is consistent with that of the cited me-too product (Effitix Tropical Solution for Dogs; EPA Reg. Nos. 2382-187); and (b) conforms to the mitigation measures stated in the Agency's letter ("Implementation of Label Changes to Pet Spot-on Products") to you, dated 09/30/2011. Also, if EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

Copy of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with the above stated conditions, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me or Dr. B. A. Akinlosotu via (703) 605-0653 or [akinlosotu.bonaventure@epa.gov](mailto:akinlosotu.bonaventure@epa.gov).

Sincerely,



Richard Gebken,  
Product Manager (RM 10)  
Insecticide Branch  
Registration Division (MC 7505P)

Enclosures  
Stamped Label

**Draft Master Label**

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Due to space limitations the layout of the 1x hanging card may differ from the 3x and 6x cartons (NOTE: The 1x hanging card will not utilize a carton or compliance cards, so all required information will be located on the Insert, blister pack or pipette for the 1x presentation). Optional text appears in brackets.

(For alternate marketing text to use on carton, insert, or 1X hanging card see pages 13-18)

(CARTON FRONT PANEL)

[1][3][6]  
monthly  
dose(s)

**TRADENAME™ for dogs**

~~(Available [through veterinarians] [from a licensed veterinary professional] [from a licensed veterinarian])~~

[From the makers of FRONTLINE®]

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 12 weeks or older and up to 22.9 lbs)

(Dogs ONLY 23 - 44.9 lbs)

(Dogs ONLY 45 - 88.9 lbs)

(Dogs ONLY 89 - 132 lbs)

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**MAY 11 2012**  
**Under the Federal Insecticide,**  
**Fungicide, and Rodenticide Act,**  
**as amended, for the pesticide**  
**registered under EPA Reg. No.**  
**65331-8**

Contains 1, 3 or 6-[(0.034 fl. oz. (1.0 ml), 0.068 fl. oz. (2.0 ml), 0.135 fl. oz. (4.0 ml), 0.203 fl. oz. (6.0 ml)] applicators

— Need full net contents for multiple pkgs.

Do Not Use on  
Cats  
Pictogram

## (CARTON BACK PANEL)

**READ THE ENTIRE LABEL BEFORE EACH USE****For the treatment and prevention of Fleas, Ticks, Mosquitoes, Biting Flies, and Lice on Dogs**

[Repels and kills (fleas) (and) ticks, including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain spotted fever), Brown dog ticks (that may transmit Ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis)].

[Kills ticks which may transmit Lyme disease, Canine Ehrlichiosis, Anaplasmosis, Rocky Mountain spotted fever, Hepatozoonosis, Babesiosis, or cause tick paralysis].

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on dogs under 12 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur and persist, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS. **DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs under 12 weeks of age. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

## (CARTON BACK PANEL)(Cont'd)

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

For use in DOGS (12 weeks old or older). To repel and kill fleas, ticks, and mosquitoes; to kill lice and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

*Open the child-resistant packaging according to the instructions found on the inside front panel of the carton. Hold applicator upright away from face and body, snap applicator tip to open. For small dogs (12 weeks or older) and weighing up to 22.9 lbs.: Part the dog's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the haircoat. For medium dogs 23-44.9 lbs. or large dogs 44-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty. For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Avoid contact with treated area until dry.*

**Frequency of Application**

Fleas, ticks, (biting and chewing) lice infestations can be controlled with monthly applications of **TRADENAME™** for Dogs. Biting flies and mosquitoes are (also) repelled by **TRADENAME™** for Dogs.

**TRADENAME™** for Dogs can start killing adult fleas within 6 hours and lasts for (up to) a month. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**TRADENAME™** for Dogs can kill ticks for (up to) a month. Apply monthly where tick control is consistently needed.

**TRADENAME™** for Dogs can kill biting and chewing lice for (up to) a month. Apply monthly where lice control is consistently needed.

**TRADENAME™** for Dogs aids in (the) control of (sarcoptic mange)/(mite infestations that may cause sarcoptic mange).

When applied monthly, **TRADENAME™** for Dogs (prevents blood feeding by) (and) (repels) biting flies and mosquitoes for up to 4 weeks (a [one] month). Kills mosquitoes for up to four weeks (a [one] month).

Wait at least 30 days before re-application of **TRADENAME™** for Dogs. Avoid contact with treated area until dry. **TRADENAME™** remains effective even after bathing, water immersion, or exposure to sunlight.

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-I  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **TRADENAME™**.

## (CARTON INSIDE FRONT PANEL)(Cont'd)

[Instructions for the 3x/6x blister pack):

**How to Apply TRADENAME™ for dogs**

Pictogram  
indicating how to  
remove applicator

Pictogram  
indicating how to  
open applicator

Pictogram  
indicating where to  
apply on the dog

**Step 1. To Remove Applicator:**

Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

**Step 2. Open Applicator**

Hold upright with foil side toward you and snap applicator tip.

**Step 3. Apply Tradename™ for dogs**

a) For small dogs (12 weeks or older) and weighing up to 22.9 lbs.: Part the dog's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the haircoat; b) For medium dogs 23-44.9 lbs. or large dogs 44-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty; c) For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Avoid contact with treated area until dry.

Questions or Comments?

Call: 1-800-660-1842,

Monday-Friday, 8am-8pm EST

(INSIDE CARTON FLAPS)

**TRADENAME™ for dogs**

(Rapidly/Quick/Quickly/Fast Acting)(Starts rapidly killing fleas in (as little as) 6 hours), and kills ticks for (up to) a month.

**TRADENAME™ for dogs** provides efficacy against fleas and ticks with a rapid (quick) onset of activity (in) (as little as) (6 hour). [The active ingredients in TRADENAME™ provide for fast acting (and long-lasting) control of fleas, ticks, chewing lice and mosquitoes (for at least 30 days) on dogs.]

**[PICTOGRAMS (icon with slash through)]**

Adult Flea  
Adult Tick  
Tick nymph  
Tick larvae  
Chewing Lice  
Mosquitoes  
Biting Flies  
Mites

**TRADENAME™** is a trademark of Merial.

©2012 Merial Limited, Duluth, GA.

All rights reserved.

(PACKAGE INSERT FRONT)

**TRADENAME™ for dogs**

For use ONLY on dogs &amp; puppies 12 weeks or older

Convenient, fast-acting, long-lasting spot-on treatment for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**Fipronil.....6.01%  
Permethrin\*.....44.88%**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See below for First Aid and Precautionary Statements.

**TRADENAME™ for dogs**Starts rapidly killing fleas in (as little as) 6 hours, and all stages of ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**

- Kills ticks which may transmit **Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Hepatozoonosis, Babesiosis**, or cause tick paralysis
- Kills and repels fleas, ticks, biting flies, chewing lice, and mosquitoes
- Effectively (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Kills adult fleas, ~~flea eggs & flea larvae~~
- Kills fleas which may cause flea allergy dermatitis
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 12 weeks or older
- [Can also be used on breeding, pregnant and lactating bitches]
- Fast-acting (in) (as little as) (6 hours)
- Long-lasting for 1 month against fleas and ticks
- Waterproof
- Convenient to use

**DO NOT USE ON CATS**Do not use on cats  
pictogram

~~Available [Through Veterinarians][from a licensed veterinary professional]-~~  
~~[from a licensed veterinarian]~~

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. To prevent harm to you and your dog, read entire label and directions before each use. Follow all directions and precautionary statements carefully. For external use on dogs only. Do not use on cats or rabbits. Do not use on other animals.

**DO NOT USE ON CATS**

## (PACKAGE INSERT FRONT)(Cont'd)

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use in dogs under 12 weeks of age. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

To kill and repel all stages of fleas and ticks, biting flies, mosquitoes and chewing lice apply topically to the skin of dogs or puppies (12 weeks or older) as follows:

(Instructions for the 1x hanging card/carton):

**How to Apply TRADENAME™ for dogs**

Pictogram indicating how to  
remove applicator

**Step 1. To Open,** use scissors to cut along dotted line of hanging card, then pull apart plastic and remove the applicator.

Pictogram indicating how to  
open applicator

**Step 2. Open Applicator**

Hold upright with foil side toward you and snap applicator tip.

Pictogram indicating where  
to apply on the dog

**Step 3. Apply TRADENAME™ for dogs**

a) For small dogs (12 weeks or older) and weighing up to 22.9 lbs.: Part the dog's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the haircoat; b) For medium dogs 23-44.9 lbs. or large dogs 44-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty. c) For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty. Avoid contact with treated area until dry.

**Questions or Comments?**

**Call: 1-800-660-1842,**

**Monday-Friday, 8am-8pm EST**

(PACKAGE INSERT BACK)

**FREQUENCY OF APPLICATION**

A monthly application of **TRADENAME™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **TRADENAME™** kills adult fleas, ~~flea eggs~~, and ~~flea larvae~~ for up to one month. **TRADENAME™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY. Do not use on cats. If ingested by a cat that has actively groomed a recently treated dog, this product may have serious harmful effects. If this occurs, contact your veterinarian immediately. Do not use on dogs under 12 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

## (PACKAGE INSERT BACK)(Cont'd)

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

**How Supplied**

For easy and convenient application, TRADENAME™ for Dogs is available in sizes for small dogs and puppies ONLY 12 weeks or older and up to 22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

EPA Reg. No. 65331-I

**Merial Limited**

3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

TRADENAME™ is a trademark of Merial.

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All rights reserved.

## (COMPLIANCE CARD)

(FRONT)

See other side for more

**TRADENAME™ for dogs**

Some tips and other information:

DO NOT USE ON CATS.

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and mites, all dogs must be treated with their own dose of **TRADENAME™**.

*Sarcoptic mange*  
^

Tick  
pictogramFlea eggs,  
larvae, and  
adult flea  
pictogramChewing louse  
pictogram

Apply according to label instructions, ensuring the product is applied to the skin. It must be applied above the shoulder blades at the base of the neck. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **TRADENAME™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Mosquito  
pictogramBiting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **TRADENAME™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **TRADENAME™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

3 months

5 stickers that read "Apply  
**TRADENAME™**", with the 6<sup>th</sup> sticker  
"Re-purchase **TRADENAME™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit **www.TRADENAME™.com**  
**TRADENAME™** is a trademark of Merial.

(LABEL ON INDIVIDUAL APPLICATOR)

**TRADENAME™ for dogs**

6.01% fipronil  
44.88% Permethrin

Application to  
dog pictogram

EPA Reg. No. 65331-I

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Lot No.

Do not use on  
cats pictogram

(LABEL ON BLISTER PACK)

**TRADENAME™ for dogs**

(S,M,L,XL)

*Lower lot limit?*

(For dogs and puppies ONLY 12 weeks or older and up to 22.9 lbs.)

(For dogs ONLY 23 - 44.9 lbs.)

(For dogs ONLY 45 - 88.9 lbs.)

(For dogs ONLY 89 - 132 lbs.)

Do not remove applicator until ready to use

EPA Reg. No. 65331-I

(0.034 fl. oz.)

(0.068 fl. oz.)

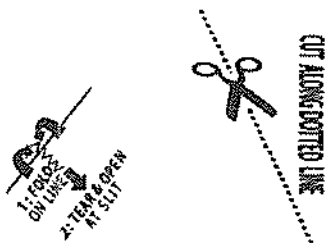
(0.135 fl. oz.)

(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Read the entire label before use

Lot No.



**Alternate marketing text for carton or insert**

**TRADENAME™ for dogs** [starts rapidly killing fleas and ticks within 6 hour providing a convenient, effective treatment for fleas and (all stages of) ticks]. **TRADENAME™** kills and repels fleas, mosquitoes, biting flies, chewing lice, and all stages of ticks; ONLY for (dogs and puppies 12 weeks or older and up to 22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs).

**(Multiple Infestations)**

- Starts rapidly killing fleas and all stages of ticks (in) (as little as) (6 hours), including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Hepatozoonosis, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas and ticks (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- 8-way protection against fleas, ticks, tick larvae, tick nymphs, mosquitoes, biting flies, lice, and mites ?
- ~~The killing of fleas and ticks is important in the prevention of disease transmission by these parasites~~
- After application, **TRADENAME™** spreads ~~naturally~~ over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **TRADENAME™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **TRADENAME™** is specially designed to spread ~~naturally~~ over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **TRADENAME™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **TRADENAME™** for Dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of mites and repels (and inhibits blood feeding) by biting flies and mosquitoes.
- **TRADENAME™** for Dogs contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repel and kill mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **TRADENAME™** for Dogs.
- Helps to relieve your dog's pain (discomfort) by controlling flea, tick and lice infestations

- Biting flies and mosquitoes are (also) repelled by **TRADE****NAME**<sup>™</sup> for Dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes
- Long lasting flea, tick and mosquito control for your pet
- **TRADE****NAME**<sup>™</sup> for Dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs 12 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of mites
- Kills and repels fleas, ticks, and mosquitoes.

## [Fleas]

- ~~Kills and repels all stages of fleas~~
- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Larval flea stages in the dog's environment (surroundings) are killed following contact with a **TRADE****NAME**<sup>™</sup> treated dog — *specific data/duration, etc. >*
- Kills fleas (before they lay eggs) (that may transmit ~~disease, including~~ bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **TRADE****NAME**<sup>™</sup> rapidly kills fleas and may reduce the incidence of this condition.
- **TRADE****NAME**<sup>™</sup> kills existing fleas on dogs within (6 hours).
- Re-Infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- ~~Repels and kills all life stages of fleas~~
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- ~~(Regular use) protects against all stages of the flea life cycle~~
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **TRADE****NAME**<sup>™</sup> rapidly kills fleas and may reduce the incidence of FAD
- **TRADE****NAME**<sup>™</sup> is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **TRADE****NAME**<sup>™</sup> breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **TRADE****NAME**<sup>™</sup> for Dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit ~~diseases, including~~ bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit ~~diseases, including~~ bartonellosis and tularemia
- ~~Rapid kill of fleas is important in the prevention of disease transmission by (these) parasites~~
- Acts to kill fleas that may transmit ~~disease, such as~~ bartonellosis and tularemia

- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **TRADENAME™** for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks) ?
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks) ?
- **TRADENAME™** for Dogs kills fleas on your dog
- Once a month topical flea control for dogs 12 weeks of age or older
- **TRADENAME™** for Dogs is indicated for the prevention and control of fleas on dogs 12 weeks of age and older
- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas ~~and the diseases they may transmit for three months~~
- Stops existing flea infestations by rapidly killing adult fleas
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **TRADENAME™** rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- ~~Controls flea problems~~
- Provides flea protection on your dog ?
- Use flea [prevention] [protection] year-round
- ~~**TRADENAME™** for Dogs controls flea infestation that may lead to painful skin irritation and bacterial infection~~

## [Ticks]

- ~~Kills all stages of ticks infesting dogs~~
- (Rapidly)(kills)(ticks)(~~including those~~)(~~vectors~~)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), (Southern Tick Associated Rash Illness), and (Hepatozoonosis)
- Kills ticks for (up to)(at least) 4 weeks
- **TRADENAME™ for dogs** rapidly kills all stages of ticks, including deer ticks, brown dog ticks, American dog ticks, and lone star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, hepatozoonosis and heartworm disease.
- Ticks: **TRADENAME™** for Dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks)

- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks

[Mosquitoes and biting flies] *Data for biting flies?*

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **TRADE NAME™** for Dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

[Lice and Mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **TRADE NAME™** for Dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Mites: (**TRADE NAME™** for Dogs) aids in (the) control of mites (that may cause sarcoptic mange)
- **TRADE NAME™** for Dogs aids in (the) control of mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **TRADE NAME™** for Dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)

- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice
- ~~(For treatment of)(kills) sarcoptic mange mites~~

## [Miscellaneous]

- **TRADENAME™** is waterproof and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- [Can also be used on breeding, pregnant and lactating bitches]
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, **TRADENAME™** for Dogs is available in sizes for small dogs (12 weeks old or older) and up to 22.9 lbs (0.034 fl oz)(1.0 ml), medium dogs 23-44.9 lbs (0.068 fl oz) (2.0 ml), large dogs 45-88.9 lbs (0.135 fl oz) (4.0 ml), and extra-large dogs 89-132 lbs (0.203 fl oz) (6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- ~~New~~ (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Tested on puppies from 12 weeks of age
- Convenient to use
- (1)(3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (1)(3)(6) applicator(s) (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- (1)(3)(6) applicator(s) (0.034 fl oz [1.0 mL] (0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- (1)(3)(6) applicator(s)(each) containing (0.034 fl oz [1.0mL], 0.068 fl oz [2.0 mL], 0.135fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- (1)(3)(6) applicator(s)
- (1)(3)(6) monthly dose(s) [application(s)]
- (1)(3)(6) applicator(s)
- This product is only for use on dogs 12 weeks of age or older up to 22.9 lbs (weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Up to 22.9 lbs (weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **TRADENAME™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- ~~Fragrance (odor) free~~
- No noticeable odors

6 months  
from NBR

- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Convenient, easy to apply and ~~fragrance free topical solution~~
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- ~~Available from licensed veterinarians~~
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)

**Draft Master Label**

**Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Optional text appears in brackets.**

(For alternate marketing text to use on carton and insert, see pages 12-17)

(CARTON FRONT PANEL)

[3][6]  
monthly  
dose(s)

**CERTISHIELD™ for dogs**

[From the makers of FRONTLINE®]

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)]

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

New raised  
label

Net Contents: 1-[0.034 fl. oz. (1.0 ml), 0.068 fl. oz. (2.0 ml), 0.135 fl. oz. ( 4.0 ml), 0.203 fl. oz. (6.0 ml)]

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl. oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

Do Not Use on  
Cats  
Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

(CARTON BACK PANEL)(CONT'D.)

Merial Limited  
3239 Satellite Blvd.  
Ouluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-8  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **CERTISHIELD™**.

(CARTON INSIDE FRONT PANEL)

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

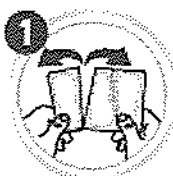
If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

**APPLICATION DIRECTIONS**

(Instructions for the 3x/6x Carton):

How to apply **CERTISHIELD™**  
FOR DOGS



**1** TO REMOVE Applicator:  
Prior to opening  
separate one blister  
by tearing along perforation.

**2**

TO OPEN,  
use scissors to cut along  
dotted line of single blister,  
then pull apart foil  
and remove the applicator.  
OR fold on line at corner,  
tear and open at slit  
and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

**Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty.

## (CARTON INSIDE FRONT PANEL)(CONT'D.)

For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

## (CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea  
Adult Tick  
Chewing Lice  
Mosquitoes  
Biting Flies  
Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and ™**CERTISHIELD** is a trademark, of Merial.

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(PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**

[1.5 x 1.5 cm]

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS**

(PACKAGE INSERT FRONT)(CONT'D.)

(Instructions for the 1x blister pack):

**To open,**  
use scissors to cut along dotted line of single blister,  
then pull apart foil and remove the applicator.

**Or**  
fold on line at corner,  
tear and open at slit and remove the applicator.

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

(PACKAGE INSERT BACK)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,

Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

**Merial Limited**

3239 Satellite Blvd.

Duluth, GA 30096-4640, USA

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## (COMPLIANCE CARD)

## (FRONT)

See other side for more

**CERTISHIELD™ for dogs**

Some tips and other information:

**DO NOT USE ON CATS.**

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Tick pictogram

Pipette pictogram

Adult flea pictogram

Chewing lice pictogram

Mosquito pictogram

Biting fly pictogram

## (BACK)

Calendar reminder stickers

Do not use on cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit **www.CERTISHIELD™.com**.

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on  
cats pictogram

(LABEL ON BLISTER PACK)

**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)

(0.068 fl. oz.)

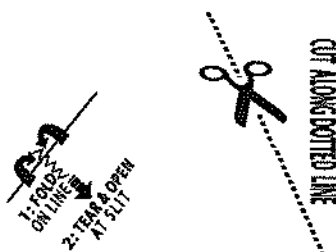
(0.135 fl. oz.)

(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



**Alternate marketing text for carton or insert**

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs.)(dogs weighing 23 – 44.9 lbs.)(dogs weighing 45 – 88.9 lbs.)(dogs weighing 89 – 132 lbs.).

[Multiple Infestations]

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas
- Stops existing flea infestations by (rapidly) killing adult fleas
- Kills fleas before they lay eggs
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity
- Use flea [prevention] [protection] year-round

#### [Ticks]

- Kills all stages of ticks infesting dogs
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness)
- Kills ticks for (up to)(at least) 4 weeks
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- Ticks: **CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks

## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome )(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (1)(3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (1)(3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (1)(3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (1)(3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (1)(3)(6) applicator(s)
- (1)(3)(6) monthly dose(s) [application(s)]
- (1)(3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)

# DATA PACKAGE BEAN SHEET

Date: 19-Dec-2012

Page 1 of 2

Decision #: 472190

DP #: (407731)

PRIA

Parent DP #:

Submission #: 927019

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 65331-8 - TRADENAME FOR DOGS

Company: 65331 - Merial Limited

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Driss Benmhend DBENMHEN

Sent Date:

PRIA Due Date: 12-Apr-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R340) AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LAE

Ingredients: 109701, Permethrin(44.88%)

129121, Fipronil(6.01%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 19-Dec-2012

Due Back:

DP Ingredient: 129121, Fipronil

109701, Permethrin

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 13-Mar-2013

Team Name: Child Resistant Packaging

Science Due Date:

Reviewer Name: Gross, Rosalind

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Hello :

I am attaching the Child Resistant Packaging data submitted by Merial in response to the agreement with RD during the meeting held on June 13, 2012. In addition to the MRIDs, I am attaching:

1. The cover letter
2. Copy of the label

Please review and comment

Thanks

Driss  
308-9525

DP#: (407731)

\*\*\* Studies Sent for Review \*\*\*

Decision#: (472190)

MRID	MRID Status	Citation Reference	Guideline	SSS Status
49000900		Meril Limited (2012) Submission of Safety Data in Support of the Registration of Certishield for Dogs. Transmittal of 2 Studies.		Pass (05-Dec-2012)
49000901		Ward, R. (2012) Evaluation of the Fold Over Tear or Scissors Blister with Flare 6x (XL) Pipette as a Poison Prevention Package for Meril Limited. Project Number: 1365/110. Unpublished study prepared by Perritt Laboratories, Inc. 27p.		Pass (05-Dec-2012)
49000902		Ward, R. (2012) Evaluation of the Fold Over Tear or Scissors Blister with Flare 1x (L) Pipette as a Poison Prevention Package for Meril Limited. Project Number: 1365/111. Unpublished study prepared by Perritt Laboratories, Inc. 27p.		Pass (05-Dec-2012)

# Decision Information for 65331-8

Decision Seq: 472190 Action Code: R340, AMENDMENT, NON-FAST TRACK, REVIEW WITHIN RD, E.G. I ...

FFS Start Date: 12-Dec-2012 Tentative Ind: No Start/Stop Clock: FQPA Clock:

Due Date: 12-Apr-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Dt: 21-Day Due Date: 12-Dec-2012 FFS Original Decision: ...

Negotiated Due Dt: 45-Day Due Date: 28-Jan-2013

Registrant: Response Due Date:

Current Status: PENDING (21-Nov-2012)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S. 827019	Benmhend, Driss	65331-8	12-Apr-2013	PENDING

GRP Studies:

Viewing Record 1 of 1

**21-Day Screen of Amendment**  
**(Completed by Contractor)**

**21-day Expires on** 12/11/12

**Document Part Of:** 65331-8  
**MRID, If Any:** 490009

**Content Screen: Recommended to**  
**Pass/Fail**

**11-3 Review: Passed/Failed/NA**

**Overall Status: Pass/Fail**

**Document returned to:**

Steve Schaible



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number  
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096

EPA Registration Number/File Symbol  
65331-8

Active Ingredient(s) and/or representative test compound(s)  
Fipronil + Permethrin

Date  
November 19, 2012

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
Indoor, non-food use

Product Name  
CERTISHIELD for dogs

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Nov. 19, 2012

Typed or Printed Name and Title

Timothy A. Dolson, Director



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Merial Limited/65331-8	2. EPA Product Manager Richard Gebkin	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CERTISHIELD for dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd., Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 2382-187 Product Name Effitix Topical Solution for Dogs	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of child-resistance and senior adult use effectiveness studies

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Printed			

## Section - IV

t. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Director, RA NPD	Telephone No. (Include Area Code) 678-638-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, RA NPD	
4. Typed Name Timothy A. Dotson	5. Date 12/19/12	

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 11/20/12

Experts In-Processing Signature: MP Date 11/23

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>65331-8</u>		EPA Receipt Date: <u>11/20/12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies passed 11-3 review.

490009

11/28/12 - An e-mail was sent to the registrant regarding the cert. form, which had a deficiency.

- Received corrected form.

TW

\* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

##### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 27, 2012

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MERIAL LIMITED  
3239 SATELLITE BLVD, BLDG 500, OFFICE 113  
DULUTH, GA 30096-4640

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 20-NOV-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 927019

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 65331 Merial Limited

Risk Manager: Registration Division, Risk Management Team 10

Product #: 65331-8

Product Name: TRADENAME FOR DOGS

Me Too Section3:

Application Date: 19-Nov-2012

Front End Date: 20-Nov-2012

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description:  
Submission of child-resistance and senior adult use effectiveness studies

Form A:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

Me Too Product Name:

OPP Rec'd Date: 20-Nov-2012

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Form B:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

Paper Label

View/Edit

Timothy A. Dotson  
Director  
Regulatory Affairs US  
Tel: 678-638-3713  
Fax: 678-638-3715

49000900



3239 Satellite Blvd.  
Duluth, GA 30096  
Tel: 678 638 3000

November 19, 2012

Mr. Richard Gebken  
Registration Division  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**SUBJECT:** CERTISHIELD™ for dogs, EPA Reg. No. 65331-8  
Submission of New Child-Resistance and Senior-Adult Use Effectiveness  
Data

Dear Mr. Gebken:

Merial is hereby submitting child-resistance (CR) and senior-adult use effectiveness studies (SAUE) for CERTISHIELD for dogs, in response to the agreement in the EPA meeting with you and Ms. Rosalind Gross held on 13Jun12, and in the EPA letter dated 03Aug12 (attached). Based on the agreements in the meeting, Merial is providing the following studies<sup>1</sup>:

- Perritt Contract No. 1365-111: Child-Resistance Effectiveness test for 4 ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-111: Senior Adult Effectiveness test for 4 ml size pipette filled with water in a single pouch with the same Senior Adult Use Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-110: Child-Resistance Effectiveness test for 6 ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-110: Senior Adult Effectiveness test for 6 ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Use Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7

The following table summarizes the results of all 4 studies:

Test	Study No.	Presentation	Size	% Effectiveness
CRE	1365-111	1x	4 ml	96.0
SAUE	1365-111	1x	4 ml	98.0
CRE	1365-110	6x	6 ml	98.0
SAUE	1365-110	6x	6 ml	99.0

<sup>1</sup> Derived from 13Jun12 meeting minutes; not actual study titles.



Although Merial requested registration of a 1x hanging card, we are hereby withdrawing that presentation for this product. Merial will only launch the 3x and 6x pipette presentations.

All 4 studies passed and provided high scores ( $\geq 96.0\%$ ) for both child-resistance and senior-adult use effectiveness. Based on these results, Merial believes the data is sufficient to “bridge” to the remaining presentations and sizes, which include the 3x presentation (all sizes: 1, 2, 4 and 6 ml), and the 1, 2 and 4 ml sizes of the 6x presentation.

In addition to the changes necessitated by the new CR/SAUE studies for instructions for opening, we have also made the following changes to the Master and facsimile labels in conformance with the registration letter and label comments (11May12), and the latest EPA-approved label for EFFITIX for dogs (dated 28Aug12; EPA Reg. No. 2382-187). We have also incorporated changes based on the EPA’s Spot-On Advisory:

- Removed the statement, “Available [through veterinarians][from a licensed veterinary professional][from a licensed veterinarian];
- Added a placeholder for a Track & Trace 2-D data matrix used to track product inventory;
- Added Net Contents to the label;
- Reconfigured the label so that critical information such as precautionary statements and First Aid can be visualized more easily—placing this information on the back of the primary carton.
  - This necessitated moving other information to other parts of the labeling, but only when in compliance with the Label Review Manual;
- Deleted all references that pertain to immature flea stages;
- Added “sarcoptic mange mites” to all references of mites;
- Removed all references to Hepatozoonosis;
- Changes made in relation to the revised EFFITIX for dogs (EPA Reg. 2382-1787) label:
  - Changed the Small dog weight range to conform to the latest EFFITIX for dogs label (EPA Reg. No. 2382-187), from “Up to 22.9 lbs.” to “11-22.9 lbs.”. This is also in conformance with the EPA’s spot-on advisory;
  - Included the new age limit of 8 weeks or older for dogs and puppies;
- Updated other aspects of the labeling to conform to the EPA’s spot-on advisory;
- Added approved marketing text on label; and,
- Other grammatical changes as needed.

Please note that the latest version of the Master text label submitted to Bonaventure Akinlosotu was dated 10May12. A copy of this label is being provided in this submission.

Volume 1 of this submission includes a cover letter, copy of the Application form (8570-1) and PRIA check, Transmittal Document, Data Certification form, Data Matrix, a child-resistant packaging (CRP) certification statement for all presentations and sizes, 1 copy of the current Master text label (dated 10May12), 5 copies of the revised Master text label (including 1 highlighted copy<sup>2</sup>) with the updated section on Instructions for Opening and other changes consistent with the EPA’s spot-on advisory (version dated 19Nov12), 1 copy of the Master facsimile labeling representing each size (S, M, L and XL) and presentation (Note: only the 3x presentation will be launched at this time<sup>3</sup>), and 3 copies of each final study report.

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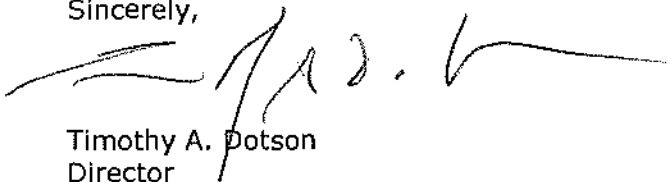
<sup>2</sup> Note: Deleted text not highlighted.

<sup>3</sup> The final printed labeling for all sizes and presentations will be submitted prior to launch.

Merial anticipates that this submission will have PRIA category R340, AMENDMENT REQUIRING DATA REVIEW WITHIN RD (E.G., CHANGES TO PRECAUTIONARY LABEL STATEMENTS). This category provides for a 4-month statutory review time. A fee of \$3,617 is being remitted now in the form of a check payable to the US EPA. A copy of the check is included in this submission.

Thank you for your assistance in this matter. Please call me at 678-638-3713 (email at [Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)) if you have any questions regarding this submission.

Sincerely,

A handwritten signature in black ink, appearing to read 'Timothy A. Dotson', with a long horizontal flourish extending to the right.

Timothy A. Dotson  
Director  
Regulatory Affairs NP US

## TRANSMITTAL DOCUMENT

**Submitter:** Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640

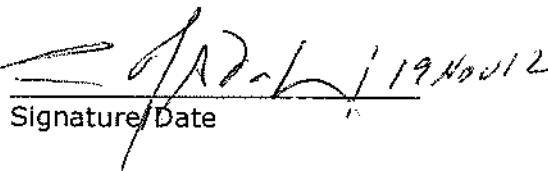
**Regulatory Action:** Submission of New Child-Resistance and Senior-Adult Use  
Effectiveness Studies for EPA Reg. No. 65331-8

**Transmittal Date:** November 19, 2012

### List of Submitted Volumes:

VOLUME	Guideline	TITLE	MRID NO.
1 of 4	NA	Administrative Materials	
2 of 4	NA	Transmittal Document	
3 of 4	40 CFR PART 157, SUBPART B	Perritt Contract No. 1365-110: Evaluation of the Fold Over Tear or Scissors Blister with FLARE 6x (XL) Pipette as a Poison Prevention Package for Merial Limited	<b>49000901</b>
4 of 4	40 CFR PART 157, SUBPART B	Perritt Contract No. 1365-111: Evaluation of the Fold Over Tear or Scissors Blister with FLARE 1x (L) Pipette as a Poison Prevention Package for Merial Limited	<b>49000902</b>

Company Official: Timothy A. Dotson  
Name

  
Signature/Date

Company Name: Merial Limited

Company Contact: Timothy A. Dotson 678-638-3713  
Name Phone

Email: timothy.dotson@merial.com



**Application Deficiency (65331-8)**

Tracy Jackson to: Timothy.Dotson

11/28/2012 10:45 AM

From: Tracy Jackson/DC/USEPA/US  
To: Timothy.Dotson@Merial.com

Dear Mr. Dotson,

I am contacting you regarding your submission of **Certishield for Dogs (65331-8)**. There was a deficiency found in the application packet.

**Application Deficiency :**

- On the Certification with Respect to Citation of Data (form 8570-34), under Section I: Method of Data Support. The box on the right should be checked.

Please send a corrected form to [jackson.tracy@epa.gov](mailto:jackson.tracy@epa.gov)

If you have any questions I can be reached at 703-308-7227

Thank you

Tracy Jackson  
Macfadden/EPA Contractor  
2777 S. Crystal Drive  
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 21, 2012

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-472190  
EPA File Symbol or Registration Number: 65331-8  
Product Name: TRADENAME FOR DOGS  
EPA Receipt Date: 20-Nov-2012  
EPA Company Number: 65331  
Company Name: Merial Limited

DR. KAREN C. CUNNINGHAM  
Merial Limited  
HEAD, REGULATORY AFFAIRS LIFECYCLE MANAGEMENT US  
3239 SATELLITE BLVD, BLDG 500, OFFICE 113  
DULUTH, GA 30096-4640

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "Teresa Owens", is written over the typed name.

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{9270191~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies?    ☐ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

927019

EPA File Symbol/Reg. No.

65331-8

Pin-Punch Date:

11/20/2012

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3617.00

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 11/21/12

Remarks:

# Receipt for Section 3

S: 927019

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 65331 MERIAL LIMITED

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 65331-8

Product Name: TRADENAME FOR DOGS

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 19-Nov-2012



OPP Rec'd Date: 20-Nov-2012



Front End Date: 20-Nov-2012



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Submission of child-resistance and senior adult use effectiveness studies

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

MERIAL LIMITED  
115 Trans Tech Drive  
Athens, GA 30601

Vendor Name ENVIRONMENTAL PROTECTION  
AGENCY  
Check Date 09-Nov-2012 Vendor Number 6830

Invoice	Invoice Date	Description	Discount	Net Amount
151516	06-Nov-2012	RE: FLARE CR/SAUE data <i>EPA Reg. No. 65331-8</i>	0.00	3,617.00
TOTAL			0.00	3,617.00

\*Commercial/financial information may be entitled to confidential treatment\*



MERIAL LIMITED  
115 Trans Tech Drive  
Athens, GA 30601  
(706) 548-9292

Check Number 569838

Citibank, N.A.  
One Penn's Way  
New Castle DE 19720

62-20  
311

Check Date

09-Nov-2012

Check Amount

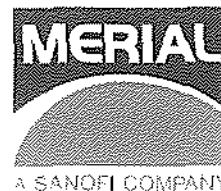
\*\*\*\*\*\$3,617.00

Pay Three Thousand Six Hundred Seventeen and 00/100 Dollars\*\*\*\*\*

To The  
r Of ENVIRONMENTAL PROTECTION AGENCY  
US BANK GOVERNMENT LOCKBOX 979074  
1005 CONVENTION PLAZA SL-MO-C2-GL  
ST LOUIS, MO 63197

*James A. Pank*  
AMOUNT OVER \$10,000.00 REQUIRE TWO SIGNATURES

Timothy A. Dotson  
Director  
Regulatory Affairs US  
Tel: 678-638-3713  
Fax: 678-638-3715



3239 Satellite Blvd.  
Duluth, GA 30096  
Tel: 678 638 3000

November 19, 2012

Mr. Richard Gebken  
Registration Division  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**SUBJECT:** CERTISHIELD™ for dogs, EPA Reg. No. 65331-8  
Submission of New Child-Resistance and Senior-Adult Use Effectiveness Data

Dear Mr. Gebken:

Merial is hereby submitting child-resistance (CR) and senior-adult use effectiveness studies (SAUE) for CERTISHIELD for dogs, in response to the agreement in the EPA meeting with you and Ms. Rosalind Gross held on 13Jun12, and in the EPA letter dated 03Aug12 (attached). Based on the agreements in the meeting, Merial is providing the following studies<sup>1</sup>:

- Perritt Contract No. 1365-111: Child-Resistance Effectiveness test for 4 ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-111: Senior Adult Effectiveness test for 4 ml size pipette filled with water in a single pouch with the same Senior Adult Use Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-110: Child-Resistance Effectiveness test for 6 ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7
- Perritt Contract No. 1365-110: Senior Adult Effectiveness test for 6 ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Use Effectiveness (SAUE) directions used in testing EPA Reg. No. 65331-7

The following table summarizes the results of all 4 studies:

Test	Study No.	Presentation	Size	% Effectiveness
CRE	1365-111	1x	4 ml	96.0
SAUE	1365-111	1x	4 ml	98.0
CRE	1365-110	6x	6 ml	98.0
SAUE	1365-110	6x	6 ml	99.0

<sup>1</sup> Derived from 13Jun12 meeting minutes; not actual study titles.



Although Merial requested registration of a 1x hanging card, we are hereby withdrawing that presentation for this product. Merial will only launch the 3x and 6x pipette presentations.

All 4 studies passed and provided high scores ( $\geq 96.0\%$ ) for both child-resistance and senior-adult use effectiveness. Based on these results, Merial believes the data is sufficient to "bridge" to the remaining presentations and sizes, which include the 3x presentation (all sizes: 1, 2, 4 and 6 ml), and the 1, 2 and 4 ml sizes of the 6x presentation.

In addition to the changes necessitated by the new CR/SAUE studies for instructions for opening, we have also made the following changes to the Master and facsimile labels in conformance with the registration letter and label comments (11May12), and the latest EPA-approved label for EFFITIX for dogs (dated 28Aug12; EPA Reg. No. 2382-187). We have also incorporated changes based on the EPA's Spot-On Advisory:

- Removed the statement, "Available [through veterinarians][from a licensed veterinary professional][from a licensed veterinarian];
- Added a placeholder for a Track & Trace 2-D data matrix used to track product inventory;
- Added Net Contents to the label;
- Reconfigured the label so that critical information such as precautionary statements and First Aid can be visualized more easily—placing this information on the back of the primary carton.
  - This necessitated moving other information to other parts of the labeling, but only when in compliance with the Label Review Manual;
- Deleted all references that pertain to immature flea stages;
- Added "sarcoptic mange mites" to all references of mites;
- Removed all references to Hepatozoonosis;
- Changes made in relation to the revised EFFITIX for dogs (EPA Reg. 2382-1787) label:
  - Changed the Small dog weight range to conform to the latest EFFITIX for dogs label (EPA Reg. No. 2382-187), from "Up to 22.9 lbs." to "11-22.9 lbs.". This is also in conformance with the EPA's spot-on advisory;
  - Included the new age limit of 8 weeks or older for dogs and puppies;
- Updated other aspects of the labeling to conform to the EPA's spot-on advisory;
- Added approved marketing text on label; and,
- Other grammatical changes as needed.

Please note that the latest version of the Master text label submitted to Bonaventure Akinlosotu was dated 10May12. A copy of this label is being provided in this submission.

Volume 1 of this submission includes a cover letter, copy of the Application form (8570-1) and PRIA check, Transmittal Document, Data Certification form, Data Matrix, a child-resistant packaging (CRP) certification statement for all presentations and sizes, 1 copy of the current Master text label (dated 10May12), 5 copies of the revised Master text label (including 1 highlighted copy<sup>2</sup>) with the updated section on Instructions for Opening and other changes consistent with the EPA's spot-on advisory (version dated 19Nov12), 1 copy of the Master facsimile labeling representing each size (S, M, L and XL) and presentation (Note: only the 3x presentation will be launched at this time<sup>3</sup>), and 3 copies of each final study report.

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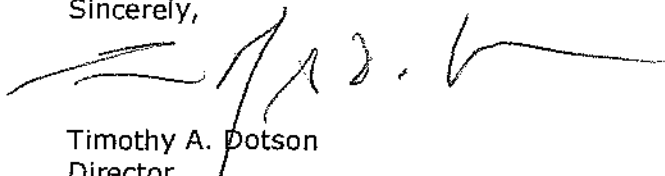
<sup>2</sup> Note: Deleted text not highlighted.

<sup>3</sup> The final printed labeling for all sizes and presentations will be submitted prior to launch.

Merial anticipates that this submission will have PRIA category R340, AMENDMENT REQUIRING DATA REVIEW WITHIN RD (E.G., CHANGES TO PRECAUTIONARY LABEL STATEMENTS). This category provides for a 4-month statutory review time. A fee of \$3,617 is being remitted now in the form of a check payable to the US EPA. A copy of the check is included in this submission.

Thank you for your assistance in this matter. Please call me at 678-638-3713 (email at [Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)) if you have any questions regarding this submission.

Sincerely,

A handwritten signature in black ink, appearing to read 'Timothy A. Dotson', written over a horizontal line.

Timothy A. Dotson  
Director  
Regulatory Affairs NP US

## TRANSMITTAL DOCUMENT

**Submitter:** Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640

**Regulatory Action:** Submission of New Child-Resistance and Senior-Adult Use  
Effectiveness Studies for EPA Reg. No. 65331-8

**Transmittal Date:** November 19, 2012

**List of Submitted Volumes:**

VOLUME	Guideline	TITLE	MRID NO.
1 of 4	NA	Administrative Materials	
2 of 4	NA	Transmittal Document	
3 of 4	40 CFR PART 157, SUBPART B	Perritt Contract No. 1365-110: Evaluation of the Fold Over Tear or Scissors Blister with FLARE 6x (XL) Pipette as a Poison Prevention Package for Merial Limited	
4 of 4	40 CFR PART 157, SUBPART B	Perritt Contract No. 1365-111: Evaluation of the Fold Over Tear or Scissors Blister with FLARE 1x (L) Pipette as a Poison Prevention Package for Merial Limited	

Company Official: Timothy A. Dotson  
Name

Signature Date

Company Name: Merial Limited

Company Contact: Timothy A. Dotson 678-638-3713  
Name Phone

Email: timothy.dotson@merial.com

### DATA MATRIX

Page 1 of 1

Product	Unit Price	Quantity	Total Price
Product A	10	5	50
Product B	20	3	60
Product C	30	2	60
Product D	40	1	40
Product E	50	1	50
Product F	60	1	60
Product G	70	1	70
Product H	80	1	80
Product I	90	1	90
Product J	100	1	100
Product K	110	1	110
Product L	120	1	120
Product M	130	1	130
Product N	140	1	140
Product O	150	1	150
Product P	160	1	160
Product Q	170	1	170
Product R	180	1	180
Product S	190	1	190
Product T	200	1	200
Product U	210	1	210
Product V	220	1	220
Product W	230	1	230
Product X	240	1	240
Product Y	250	1	250
Product Z	260	1	260
Product AA	270	1	270
Product AB	280	1	280
Product AC	290	1	290
Product AD	300	1	300
Product AE	310	1	310
Product AF	320	1	320
Product AG	330	1	330
Product AH	340	1	340
Product AI	350	1	350
Product AJ	360	1	360
Product AK	370	1	370
Product AL	380	1	380
Product AM	390	1	390
Product AN	400	1	400
Product AO	410	1	410
Product AP	420	1	420
Product AQ	430	1	430
Product AR	440	1	440
Product AS	450	1	450
Product AT	460	1	460
Product AU	470	1	470
Product AV	480	1	480
Product AW	490	1	490
Product AX	500	1	500
Product AY	510	1	510
Product AZ	520	1	520
Product BA	530	1	530
Product BB	540	1	540
Product BC	550	1	550
Product BD	560	1	560
Product BE	570	1	570
Product BF	580	1	580
Product BG	590	1	590
Product BH	600	1	600
Product BI	610	1	610
Product BJ	620	1	620
Product BK	630	1	630
Product BL	640	1	640
Product BM	650	1	650
Product BN	660	1	660
Product BO	670	1	670
Product BP	680	1	680
Product BQ	690	1	690
Product BR	700	1	700
Product BS	710	1	710
Product BT	720	1	720
Product BU	730	1	730
Product BV	740	1	740
Product BW	750	1	750
Product BX	760	1	760
Product BY	770	1	770
Product BZ	780	1	780
Product CA	790	1	790
Product CB	800	1	800
Product CC	810	1	810
Product CD	820	1	820
Product CE	830	1	830
Product CF	840	1	840
Product CG	850	1	850
Product CH	860	1	860
Product CI	870	1	870
Product CJ	880	1	880
Product CK	890	1	890
Product CL	900	1	900
Product CM	910	1	910
Product CN	920	1	920
Product CO	930	1	930
Product CP	940	1	940
Product CQ	950	1	950
Product CR	960	1	960
Product CS	970	1	970
Product CT	980	1	980
Product CU	990	1	990
Product CV	1000	1	1000
Product CW	1010	1	1010
Product CX	10		

**CERTISHIELD™ for dogs**

[illegible]

Date	
------	--

12/19/12

### DATA MATRIX

Date November 19, 2012	EPA Reg. No./File Symbol 65331-8	Page t of t			
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product CERTISHIELD™ for dogs				
Ingredient:: Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
Signature	Name and Title Timothy A. Dotson, Director, Reg. Affairs US			Date 12/19/12	

**Draft Master Label**

**Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 3x and 6x applicator presentation. Optional text appears in brackets.**

(For alternate marketing text to use on carton and insert, see pages 11-16)

(CARTON FRONT PANEL)

# **CERTISHIELD™ for dogs**

**[From the makers of FRONTLINE®]**

[3][6]  
monthly  
dose(s)

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

## **KEEP OUT OF REACH OF CHILDREN**

### **CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

### **ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.809 fl. oz. (24.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 fl. oz. (24.0 ml), 1.618 fl. oz. (48.0 ml)]

Do Not Use on  
Cats  
Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

(CARTON BACK PANEL)(CONT'D.)

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-8  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **CERTISHIELD™**.

(CARTON INSIDE FRONT PANEL)

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

**APPLICATION DIRECTIONS**

(Instructions for the 3x/6x Carton):

How to Apply CERTISHIELD™ for dogs

**Step 1: TO REMOVE** Applicator: Prior to opening, separate one blister by tearing along perforation.

**Step 2: TO OPEN**, use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. OR fold on line at corner, tear and open at slit and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

**Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea

Adult Tick

Chewing Lice

Mosquitoes

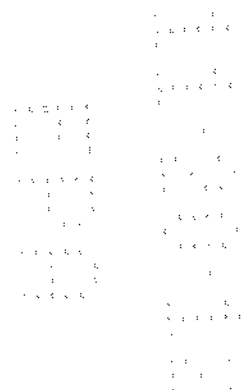
Biting Flies

Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and **™CERTISHIELD** is a trademark, of Merial.

©2012 Merial Limited, Duluth, GA.

All rights reserved.



(PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**  
[1.5 x 1.5 cm]**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

## (PACKAGE INSERT BACK)

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,

Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

**Merial Limited**

3239 Satellite Blvd.

Duluth, GA 30096-4640, USA

**CERTISHIELD™** is a trademark of Merial.

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## (COMPLIANCE CARD)

(FRONT)

See other side for more

**CERTISHIELD™ for dogs**

Some tips and other information:

**DO NOT USE ON CATS.**

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Tick  
pictogramPipette  
pictogramAdult flea  
pictogramChewing lice  
pictogramMosquito  
pictogramBiting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

-----  
3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-650-1842, Monday-Friday, 8am-8pm. For more information, visit **www.CERTISHIELD™.com**.

**CERTISHIELD™** is a trademark of Merial.

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on  
cats pictogram

(LABEL ON BLISTER PACK)

**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)

(0.068 fl. oz.)

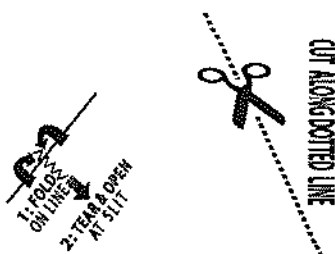
(0.135 fl. oz.)

(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



**Alternate marketing text for carton or insert**

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs).

## [Multiple Infestations]

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites
- Kills and repels fleas, ticks, and mosquitoes.

## [Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas
- Stops existing flea infestations by (rapidly) killing adult fleas
- Kills fleas before they lay eggs
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity
- Use flea [prevention] [protection] year-round

#### [Ticks]

- Kills all stages of ticks infesting dogs
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness)
- Kills ticks for (up to)(at least) 4 weeks
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- Ticks: **CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks

CERTISHIELD™  
 for dogs  
 Kills fleas before they lay eggs  
 Kills and repels ticks  
 Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.  
 Ticks: CERTISHIELD™ for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.  
 Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)  
 Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)  
 Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).  
 Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).  
 Monthly application against ticks

## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

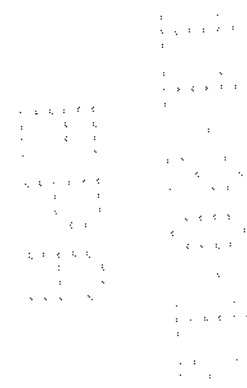
## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)
- (3)(6) monthly dose(s) [application(s)]
- (3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)



**Draft Master Label**

**Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 3x and 6x applicator presentation. Optional text appears in brackets.**

(For alternate marketing text to use on carton and insert, see pages 11-16)

(CARTON FRONT PANEL)

[3][6]  
monthly  
dose(s)

**CERTISHIELD™ for dogs**  
[From the makers of FRONTLINE®]

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl. oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

Do Not Use on  
Cats  
Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

**DO NOT USE ON CATS PICTOGRAM** [1.5 x 1.5 cm]

**DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.**

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

(CARTON BACK PANEL)(CONT'D.)

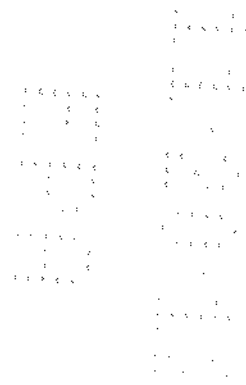
Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-8  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **CERTISHIELD™**.



(CARTON INSIDE FRONT PANEL)

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

#### **DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

### **APPLICATION DIRECTIONS**

(Instructions for the 3x/6x Carton):

How to Apply CERTISHIELD™ for dogs

**Step 1: TO REMOVE** Applicator: Prior to opening, separate one blister by tearing along perforation.

**Step 2: TO OPEN**, use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. OR fold on line at corner, tear and open at slit and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

#### **Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea

Adult Tick

Chewing Lice

Mosquitoes

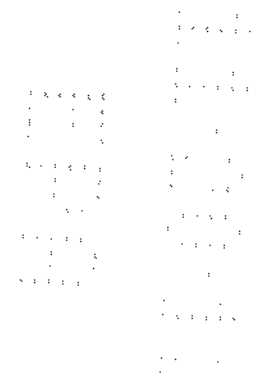
Biting Flies

Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and ™**CERTISHIELD** is a trademark, of Merial.

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## (PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**  
[1.5 x 1.5 cm]**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.**

**DO NOT USE ON CATS**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

## (PACKAGE INSERT BACK)

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,  
Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

**Merial Limited**  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

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## (COMPLIANCE CARD)

(FRONT)

See other side for more

**CERTISHIELD™ for dogs**

Some tips and other information:

DO NOT USE ON CATS.

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Tick  
pictogramPipette  
pictogramAdult flea  
pictogramChewing lice  
pictogramMosquito  
pictogramBiting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

-----  
3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit **www.CERTISHIELD™.com**.

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on  
cats pictogram

(LABEL ON BLISTER PACK)

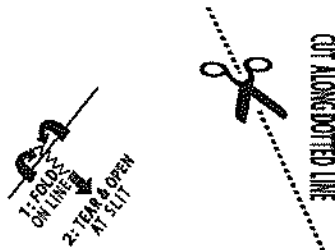
**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)  
(0.068 fl. oz.)  
(0.135 fl. oz.)  
(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



**Alternate marketing text for carton or insert**

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs).

## [Multiple Infestations]

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites
- Kills and repels fleas, ticks, and mosquitoes.

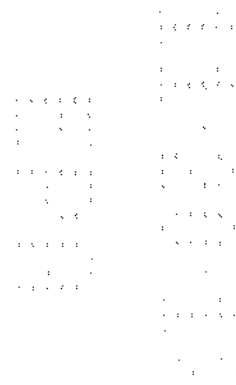
## [Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas
- Stops existing flea infestations by (rapidly) killing adult fleas
- Kills fleas before they lay eggs
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity
- Use flea [prevention] [protection] year-round

## [Ticks]

- Kills all stages of ticks infesting dogs
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness)
- Kills ticks for (up to)(at least) 4 weeks
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- Ticks: **CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks



## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)
- (3)(6) monthly dose(s) [application(s)]
- (3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application.
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)

[illegible]

**Draft Master Label**

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 3x and 6x applicator presentation. Optional text appears in brackets.

(For alternate marketing text to use on carton and insert, see pages 11-16)

(CARTON FRONT PANEL)

**CERTISHIELD™ for dogs**  
**[From the makers of FRONTLINE®]**

[3][6]  
monthly  
dose(s)

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl. oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

Do Not Use on  
Cats  
Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

Meril Limited.  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

Satisfaction  
Guaranteed  
Graphic

Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, mosquito, biting fly and lice control or **CERTISHIELD™**.

(CARTON INSIDE FRONT PANEL)

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

### APPLICATION DIRECTIONS

(Instructions for the 3x/6x Carton):

How to Apply CERTISHIELD™ for dogs

**Step 1: TO REMOVE** Applicator: Prior to opening, separate one blister by tearing along perforation.

**Step 2: TO OPEN**, use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. OR fold on line at corner, tear and open at slit and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

**Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea

Adult Tick

Chewing Lice

Mosquitoes

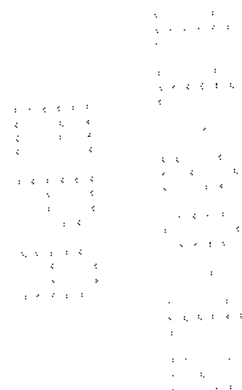
Biting Flies

Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and ™**CERTISHIELD** is a trademark, of Merial.

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(PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**  
[1.5 x 1.5 cm]**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DDGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

## (PACKAGE INSERT BACK)

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton.)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,  
Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

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(COMPLIANCE CARD

(FRONT

Tick  
pictogram

See other side for more

**CERTISHIELD™ for dogs**Pipette  
pictogramAdult flea  
pictogram

Some tips and other information:

DO NOT USE ON CATS.

Chewing lice  
pictogram

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Mosquito  
pictogram

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Biting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

-----  
3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit [www.CERTISHIELD.com](http://www.CERTISHIELD.com).

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on  
cats pictogram

(LABEL ON BLISTER PACK)

**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)

(0.068 fl. oz.)

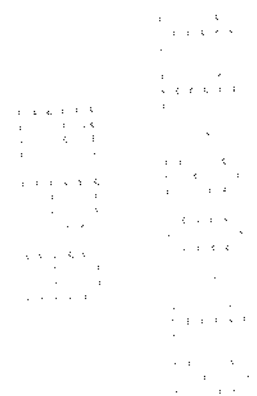
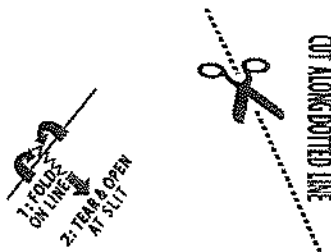
(0.135 fl. oz.)

(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



## Alternate marketing text for carton or insert:

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs).

## [Multiple Infestations]

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet.
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older.
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites.
- Kills and repels fleas, ticks, and mosquitoes.

## [Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas
- Stops existing flea infestations by (rapidly) killing adult fleas
- Kills fleas before they lay eggs
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity
- Use flea [prevention] [protection] year-round

#### [Ticks]

- Kills all stages of ticks infesting dogs
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness)
- Kills ticks for (up to)(at least) 4 weeks
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- Ticks: **CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks

CERTISHIELD™  
 for dogs  
 Kills fleas before they lay eggs  
 Kills all stages of ticks infesting dogs  
 Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.  
 Kills and repels ticks  
 Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)  
 Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)  
 Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).  
 Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).  
 Monthly application against ticks

## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome )(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex spp*, *Ochlerotatus spp*, *Aedes spp*) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

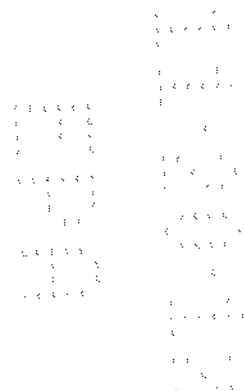
## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing swimming (water immersion) or after exposure to rain or sunlight
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)
- (3)(6) monthly dose(s) [application(s)]
- (3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)



**Draft Master Label**

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 3x and 6x applicator presentation. Optional text appears in brackets.

(For alternate marketing text to use on carton and insert, see pages 11-16)

(CARTON FRONT PANEL)

**CERTISHIELD™ for dogs**  
**[From the makers of FRONTLINE®]**

[3][6]  
 monthly  
 dose(s)

Picture of  
 representative  
 size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl. oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

Do Not Use on  
 Cats  
 Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

(CARTON BACK PANEL)(CONT'D.)

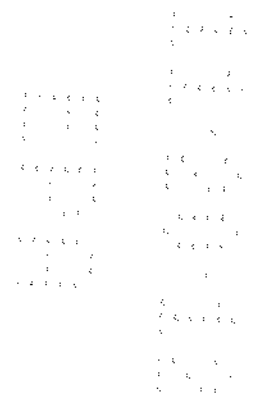
Meriel Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-F  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **CERTISHIELD™**.



(CARTON INSIDE FRONT PANEL)

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

### APPLICATION DIRECTIONS

(Instructions for the 3x/6x Carton):

How to Apply CERTISHIELD™ for dogs

**Step 1: TO REMOVE** Applicator: Prior to opening, separate one blister by tearing along perforation.

**Step 2: TO OPEN**, use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. OR fold on line at corner, tear and open at slit and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

**Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea

Adult Tick

Chewing Lice

Mosquitoes

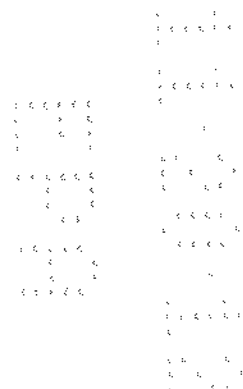
Biting Flies

Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and ™**CERTISHIELD** is a trademark, of Merial.

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## (PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**

[1.5 x 1.5 cm]

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

## (PACKAGE INSERT BACK)

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,  
Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

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(COMPLIANCE CARD)

(FRONT)

Tick  
pictogram

See other side for more

**CERTISHIELD™ for dogs**Pipette  
pictogramAdult flea  
pictogram

Some tips and other information:

**DO NOT USE ON CATS.**Chewing lice  
pictogram

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Mosquito  
pictogram

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Biting fly  
pictogram

(BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

-----  
3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit [www.CERTISHIELD.com](http://www.CERTISHIELD.com).

**CERTISHIELD™** is a trademark of Merial.

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on  
cats pictogram

[illegible]

(LABEL ON BLISTER PACK)

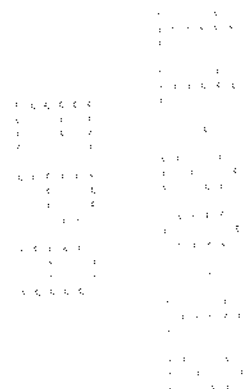
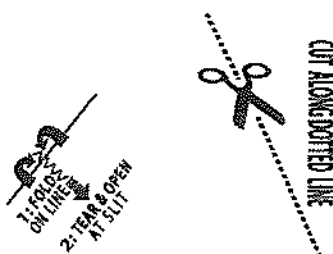
**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)  
(0.068 fl. oz.)  
(0.135 fl. oz.)  
(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



## Alternate marketing text for carton or insert:

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs)(dogs weighing 23 – 44.9 lbs)(dogs weighing 45 – 88.9 lbs)(dogs weighing 89 – 132 lbs).

## [Multiple Infestations]

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites
- Kills and repels fleas, ticks, and mosquitoes

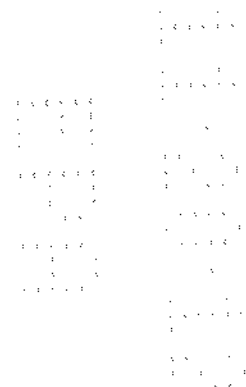
#### [Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months).
- Monthly treatment (all year) is recommended for control and prevention of fleas.
- Provides ongoing protection against fleas.
- Stops existing flea infestations by (rapidly) killing adult fleas.
- Kills fleas before they lay eggs.
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs).
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity.
- Use flea [prevention] [protection] year-round.

#### [Ticks]

- Kills all stages of ticks infesting dogs.
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness).
- Kills ticks for (up to)(at least) 4 weeks.
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks.
- Kills and repels ticks.
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- Ticks: **CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis).
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks.



## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome )(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

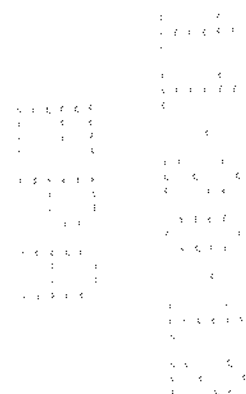
## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing swimming (water immersion) or after exposure to rain or sunlight
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (3)(6) applicator(s)
- (3)(6) monthly dose(s) [application(s)]
- (3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)



FRONT

From the makers of **FRONTLINE®**

# CERTISHIELD™

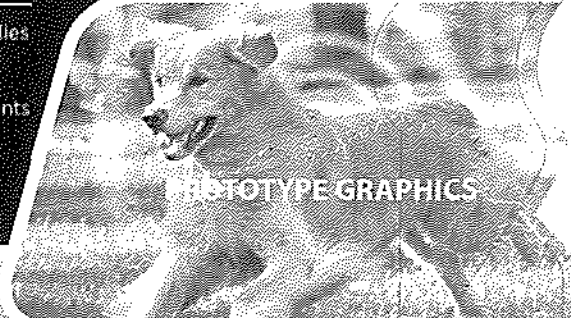
## FOR DOGS

**REPELS + KILLS**  
fleas, ticks, mosquitoes, biting flies & kills chewing lice

**3(6)**  
monthly  
doses

**FAST-ACTING • LONG-LASTING • REPELLANT**

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks including those which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis



PHOTOTYPE GRAPHICS

**DOGS ONLY**  
**45-88.9** LBS

Net Contents: 3(6)-0.135 fl. oz.  
(4.0 ml) applicators

**ACTIVE INGREDIENTS:**

Fipronil: 6.01%  
Permethrin\*: 44.88%  
OTHER INGREDIENTS: 49.11%  
TOTAL: 100%

\*is-b-trans ratio: max. 35% (+/-) is and min. 45% (+/-) trans

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

READ THE ENTIRE LABEL BEFORE EACH USE



**DO NOT USE ON CATS**



**CERTISHIELD™**  
FOR DOGS

For Dogs ONLY  
**45-88.9** LBS  
**3(6)** MONTHLY DOSES

For Dogs & Puppies ONLY  
**8 weeks or older and**  
**11-22.9** LBS

**DOGS AND PUPPIES ONLY 8 WEEKS OR OLDER AND**

**11-22.9** LBS

Net Contents: 3(6)-0.034 fl. oz.  
(1.0 ml) applicators

**SMALL DOGS**

For Dogs ONLY  
**23-44.9** LBS

**DOGS ONLY**  
**23-44.9** LBS

Net Contents: 3(6)-0.068 fl. oz.  
(2.0 ml) applicators

**MEDIUM DOGS**

For Dogs ONLY

**89-132** LBS  
**DOGS ONLY**  
**89-132** LBS

Net Contents: 3(6)-0.203 fl. oz.  
(6.0 ml) applicators

**EXTRA LARGE DOGS**

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and CERTISHIELD is a registered trademark of Merial.  
FRONTLINE is a registered trademark of Merial.

**CERTISHIELD™**  
FOR DOGS  
Repels and kills fleas, ticks, mosquitoes, and  
biting flies, and kills chewing lice for up to  
a month. Fleas do not have to bite to die.

For Dogs ONLY  
45-88.9 LBS  
3(6) monthly doses

**CERTISHIELD™**  
FOR DOGS

**CERTISHIELD™**  
FOR DOGS

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS and DOMESTIC ANIMALS**

**HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.



**DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.**

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, mosquito, biting fly and lice control or CERTISHIELD™.

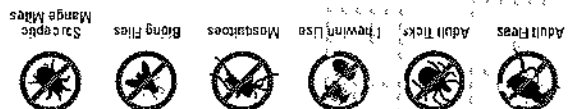


FIRST AID	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</p>	

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA EPA Reg. No. 65331-8  
MADE IN FRANCE EPA Est. No. 65331-FR-2

For Dogs ONLY  
45-88.9 LBS  
3(6) monthly doses

**CERTISHIELD™**  
FOR DOGS



CERTISHIELD™ for Dogs provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients of CERTISHIELD™ provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

For Dogs & Puppies ONLY  
8 weeks or older  
11-22.9 LBS

SMALL DOGS

For Dogs ONLY  
23-44.9 LBS

MEDIUM DOGS

BACK

For Dogs ONLY  
89-132 LBS

EXTRA LARGE DOGS

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

### How to apply **CERTISHIELD™** FOR DOGS



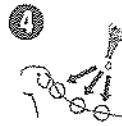
**1 TO REMOVE Applicator:**  
Prior to opening, separate one blister by tearing along perforation.



**3 HOLD Applicator Upright**  
away from you and your pet's face, cut applicator tip with scissors to open. Do not get the product in your dog's eyes or mouth.

**2**

**TO OPEN,**  
use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. OR fold on line of corner, tear and open at slit and remove the applicator.



#### APPLY CERTISHIELD™

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for Dogs is not applied superficially on dog's hair.

**MEDIUM and  
LARGE DOGS**

INSIDE



#### APPLY CERTISHIELD™

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. Ensure that CERTISHIELD™ for Dogs is not applied superficially on dog's hair.

**SMALL  
DOGS**



#### APPLY CERTISHIELD™

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for Dogs is not applied superficially on dog's hair.

**EXTRA LARGE  
DOGS**

From the makers of **FRONTLINE®**

## **CERTISHIELD™** FOR DOGS

For use **ONLY** on dogs and puppies 8 weeks or older  
Convenient, fast-acting, long-lasting spot-on for treatment  
and control of fleas, ticks, mosquitoes, biting flies and  
chewing lice

### ACTIVE INGREDIENTS

Fipronil .....6.01%

Permethrin\* .....44.88%

OTHER INGREDIENTS .....49.11%

TOTAL .....100.0%

\*cis/trans ratio: max 55% [±] cis and min 45% [±] trans

### KEEP OUT OF REACH OF CHILDREN CAUTION

See Carton for First Aid and Precautionary Statements.

#### CERTISHIELD™ for Dogs

Repels and kills fleas, ticks, and mosquitoes; repels biting flies  
and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Oer** ticks, **Brown** Dog ticks, **American** Dog ticks, and **Lone Star** ticks
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

### DO NOT USE ON CATS



#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS**

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing



★ 3 9 0 5 3 5 0 ★

FRONT

your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

Open the child-resistant packaging according to the instructions found on the inside front panel of the carton.

#### FREQUENCY OF APPLICATION

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™** for Dogs. Biting flies and mosquitoes are repelled by **CERTISHIELD™** for Dogs. **CERTISHIELD™** for Dogs can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if re-infestation is likely.

**CERTISHIELD™** for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™** for Dogs can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™** for Dogs aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™** for Dogs repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™** for Dogs. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that

**CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

#### PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL.** If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL.** If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

#### How Supplied

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies **ONLY** 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

#### WARRANTY

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

#### Questions or Comments?

Call: 1-800-660-1842.

Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

Merial Limited

3239 Satellite Blvd

Duluth, GA 30096-4640, USA

**CERTISHIELD™**

is a trademark of Merial.

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BACK

FRONT

Remove the adhesive backing and attach to your refrigerator door  
SEE OTHER SIDE FOR MORE

# CERTISHIELD™

Some tips and other information: **FOR DOGS**

**DO NOT USE ON CATS**

- ✓ To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of CERTISHIELD™.
- ✓ Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.
- ✓ Remember, your dog needs to be dry at the time CERTISHIELD™ is applied and remain dry 24 hours after application.
- ✓ Verify applicator is empty after applying to your dog.
- ✓ Even indoor dogs need tick and flea control because you or other dogs in the household may bring ticks and fleas into the home.



Ticks

Fleas

Chewing lice

Mosquitoes

Biting flies



BACK

# CERTISHIELD™

Calendar reminder stickers **FOR DOGS**

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase CERTISHIELD™.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply CERTISHIELD™ monthly. Don't forget to re-purchase!

**DO NOT USE ON CATS**



**QUESTIONS?**  
Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-5pm. For more information, visit [www.CERTISHIELD.com](http://www.CERTISHIELD.com)



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All Rights Reserved.

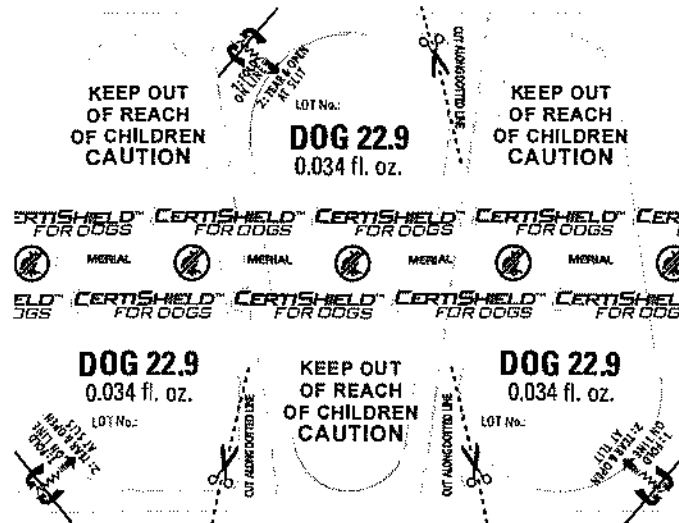
**6 Months**  
use all 6 stickers

**3 Months**

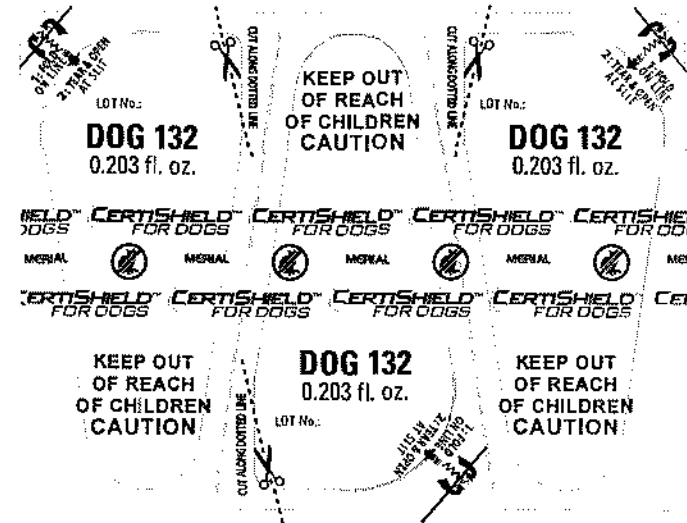
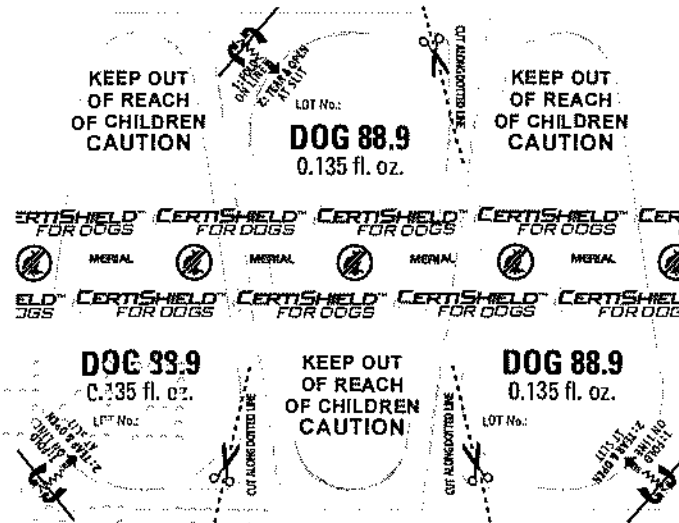
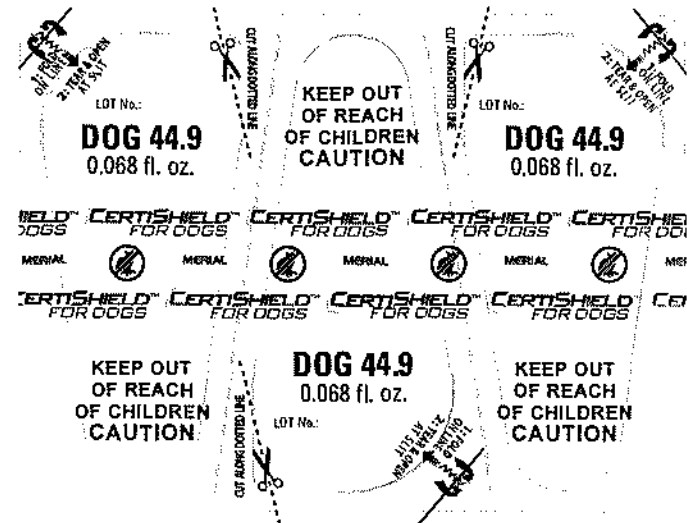





Small



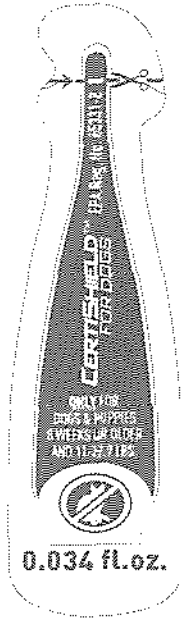
Medium



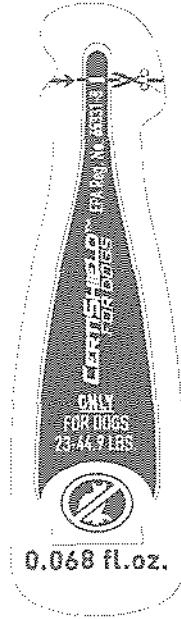
Large

X Large

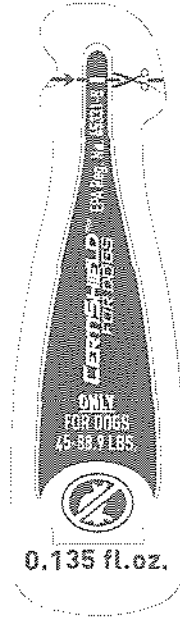
Permethrin side



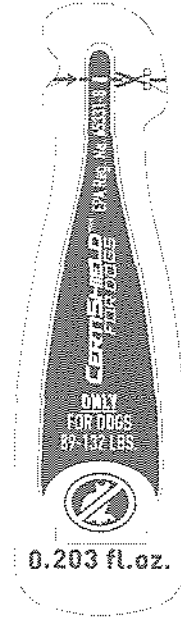
Small dog



Medium dog

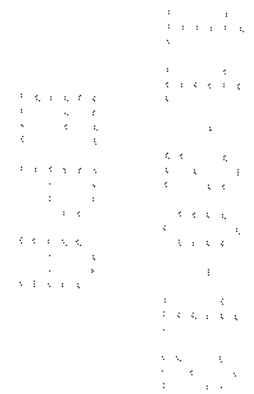
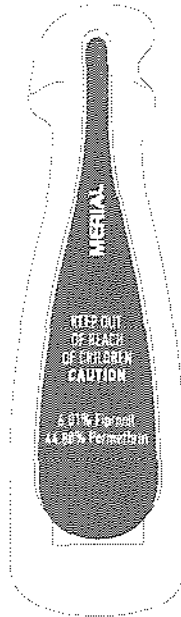


Large dog



XLarge dog

Fipronil side - ALL SIZES





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 3, 2012

**Certified Mail: 7008 3230 0000 9482 3340**

Timothy (Tim) A. Dotson, Director  
Regulatory Affairs US  
Merial Limited  
3239 Satellite Boulevard, Building 500  
Duluth, GA 30096-4640

**Subject:** Meeting of June 13 2012, discussing a proposal to self certify another packaging design other than the Frontline Packaging similar to the *FRONTLINE® Plus For Dogs*, EPA Reg. No. 65331-5 which was utilized for purposes of registration of EPA Reg. No. 65331-8.

**Product Name:** Tradename for Dogs

**EPA registration No.:** 65331-8.

Dear Mr. Dotson;

The Agency has reviewed and discussed Merial's Child Resistant Packaging (CRP) self certification proposal presented at the June 13, 2012 meeting at the Office of Pesticide Program's Offices. The Agency cannot accept this proposal, and have determined that additional data will be required per the documentation written by Rosalind Gross (attached). This documentation does not consider any other variant fill weights, or unit packaging than those presented at the June 13, 2012 meeting. Such variants may require additional CRP and/or Companion Animal Safety Studies (CASS) to adequately address the data requirements. When conducting CRP packaging testing, please follow the guidance document attached with this letter. Since **these studies are not part of the conditions of registration**, they must be submitted in accordance with the Pesticide Registration Improvement Act (PRIA), which is part of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA).

Regards,

Richard J. Gebken  
Product Manager PM10  
Office of Pesticide Programs

Attachment: Rosalind Gross memo entitled "EPA Registration Number 65331-8 Additional Data Requirements Per June 13, 2012 Meeting with Merial"

# EPA Registration Number 65331-8

## Additional Data Requirements

Per June 13, 2012 Meeting with Merial

EPA Registration Number 65331-8 is currently registered as a single pipette (1x) hanging card and a 3x and 6x blister card. The single pipette (1x) is the same shape and style green pipette and hanging card as is used on Frontline Plus EPA Registration Number 65331-5. The 3x and 6x blister card has the same shape and style green pipette and blister packaging as is used on Frontline Plus EPA Registration Number 65331-5.

At a June 13, 2012 meeting Merial indicated they are not currently marketing this package. Merial stated they want to market the product in a 1, 2, 4, and 6 ml filled pipette with a single chamber resembling the two chamber pipette used for EPA Registration Number 65331-7. Furthermore, they want these pipettes to be in the same pouches used for EPA Registration Number 65331-7 and to be sold as a 1x, 3x, and 6x size package. EPA Registration Number 65331-7 pipette sizes are 1.07ml, 2.14ml, 4.28ml, and 6.42ml. It was agreed at the meeting that the differences in the pipette and pouch used for 65331-7 versus the ones to be used for 65331-8 would require additional CRP test data. The test data would need to include at a minimum the following:

- Child-Resistant Effectiveness test for 4ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Senior Adult Effectiveness test for 4ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Child-Resistant Effectiveness test for 6ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Senior Adult Effectiveness test for 6ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7

The additional data was **conditionally limited to the 4 aforementioned studies, provided the results were not marginal passes** per 16 CFR 1700.15(b) and

1700.20. If the results were **marginal passes** per 16 CFR 1700.15(b) and 1700.20 **more testing could be required**. Merial is not marketing the product under its currently approved packaging (resembling Frontline Plus, EPA Registration Number 65331-5). The new packaging (1, 2, 4, and 6 ml filled pipette with a single chamber in a pouch resembling the two chamber pipette and pouch used for EPA Registration Number 65331-7) should be evaluated as a **replacement package not as an additional/alternate package**. This would mean that EPA Registration Number 65331-8 could not be marketed in a package (resembling Frontline Plus, EPA Registration Number 65331-5).

1700.20. If the results were **marginal passes** per 16 CFR 1700.15(b) and 1700.20 **more testing could be required**. Merial is not marketing the product under its currently approved packaging (resembling Frontline Plus, EPA Registration Number 65331-5). The new packaging (1, 2, 4, and 6 ml filled pipette with a single chamber in a pouch resembling the two chamber pipette and pouch used for EPA Registration Number 65331-7) should be evaluated as a **replacement package not as an additional/alternate package**. This would mean that EPA Registration Number 65331-8 could not be marketed in a package (resembling Frontline Plus, EPA Registration Number 65331-5).

**Draft Master Label**

**Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Optional text appears in brackets.**

(For alternate marketing text to use on carton and insert, see pages 12-17)

(CARTON FRONT PANEL)

**CERTISHIELD™ for dogs**  
**[From the makers of FRONTLINE®]**

[3][6]  
monthly  
dose(s)

Picture of  
representative  
size dog

[Fast-Acting, long-lasting control of fleas, ticks, lice, biting flies and mosquitoes for use on (Dogs & Puppies ONLY 8 weeks or older and 11-22.9 lbs.)]

(Dogs ONLY 23 – 44.9 lbs.)

(Dogs ONLY 45 – 88.9 lbs.)

(Dogs ONLY 89 – 132 lbs.)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

For First Aid and other precautionary statements, refer to product package insert.

**READ THE ENTIRE LABEL BEFORE EACH USE**

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents: 1-[0.034 fl. oz. (1.0 ml), 0.068 fl. oz. (2.0 ml), 0.135 fl. oz. ( 4.0 ml), 0.203 fl. oz. (6.0 ml)]

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl. oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

Do Not Use on  
Cats  
Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

(CARTON BACK PANEL)

**CERTISHIELD™ for dogs****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS - IF INGESTED BY A CAT THAT HAS ACTIVELY GROOMED A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Do not use on puppies under 8 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

<b>FIRST AID</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

(CARTON BACK PANEL)(CONT'D.)

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

MADE IN FRANCE

EPA Reg. No. 65331-8  
EPA Est. No. 65331-FR-2

Satisfaction  
Guaranteed  
Graphic

Please call our experts at  
1-800-660-1842 if you have any  
questions or comments about flea,  
tick, mosquito, biting fly and lice  
control or **CERTISHIELD™**.

(CARTON INSIDE FRONT PANEL)

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.**

**FOR EXTERNAL USE ON DOGS and PUPPIES ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied.

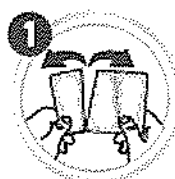
If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than once a month.

For use in DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill chewing lice and to aid in control of sarcoptic mange mites; to repel and prevent blood feeding by biting flies. Apply monthly according to the following directions:

**APPLICATION DIRECTIONS**

(Instructions for the 3x/6x Carton):

How to apply **CERTISHIELD™**  
FOR DOGS



**1 TO REMOVE Applicator:**  
Prior to opening  
separate one blister  
by tearing along perforation.

**2**

**TO OPEN,**  
use scissors to cut along  
dotted line of single blister,  
then pull apart foil  
and remove the applicator.  
**OR** fold on line at corner,  
tear and open at slit  
and remove the applicator.

**Step 3: HOLD Applicator Upright** away from you and your pet's face, cut applicator tip to open. Do not get the product in your dog's eyes or mouth.

**Step 4: Apply CERTISHIELD™**

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies (8 weeks or older) and weighing 11-22.9 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 23-44.9 lbs. or large dogs 45-88.9 lbs.: Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty.

(CARTON INSIDE FRONT PANEL)(CONT'D.)

For extra-large dogs 89-132 lbs.: Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that CERTISHIELD™ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

**CERTISHIELD™ for dogs**

Repels and kills fleas, ticks, mosquitoes, and biting flies, and kills chewing lice for up to a month. Fleas do not have to bite to die.

**CERTISHIELD™ for dogs** provides efficacy against fleas and ticks with a rapid onset of activity in as little as 6 hours. The active ingredients in **CERTISHIELD™** provide for fast acting and long-lasting control of fleas, ticks, chewing lice and mosquitoes on dogs.

**[PICTOGRAMS (icon with slash through)]**

Adult Flea  
Adult Tick  
Chewing Lice  
Mosquitoes  
Biting Flies  
Sarcoptic mange mites

®**FRONTLINE** is a registered trademark, and ™**CERTISHIELD** is a trademark, of Merial.  
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All rights reserved.

(PACKAGE INSERT FRONT)

**CERTISHIELD™ for dogs**

For use ONLY on dogs and puppies 8 weeks or older

Convenient, fast-acting, long-lasting spot-on for treatment and control of fleas, ticks, mosquitoes, biting flies and chewing lice

**ACTIVE INGREDIENTS**

Fipronil.....6.01%

Permethrin\*.....44.88%

**OTHER INGREDIENTS**.....49.11%**TOTAL**.....100.0%

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See Carton for First Aid and Precautionary Statements.

**CERTISHIELD™ for Dogs**

Repels and kills fleas, ticks, and mosquitoes; repels biting flies and kills chewing lice

- Repels and prevents blood feeding by biting flies and mosquitoes for up to a month
- Persistent efficacy through 30 days
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Rapidly kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Starts rapidly killing fleas in as little as 6 hours, and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, tularemia and tapeworm
- Repels and kills mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*) for one month
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 8 weeks or older
- Fast-acting
- Convenient to use

Do not use on cats  
pictogram**DO NOT USE ON CATS**  
[1.5 x 1.5 cm]**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.**

**DO NOT USE ON CATS**

(PACKAGE INSERT FRONT)(CONT'D.)

(Instructions for the 1x blister pack):

**To open,**  
use scissors to cut along dotted line of single blister,  
then pull apart foil and remove the applicator.

**Or**  
fold on line at corner,  
tear and open at slit and remove the applicator.

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

**FOR EXTERNAL USE ON DOGS ONLY.** Do not use on dogs or puppies under 8 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

(PACKAGE INSERT BACK)

**FREQUENCY OF APPLICATION**

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™ for Dogs**. Biting flies and mosquitoes are repelled by **CERTISHIELD™ for Dogs**.

**CERTISHIELD™ for Dogs** can start killing adult fleas within 6 hours and lasts for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

**CERTISHIELD™ for Dogs** can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

**CERTISHIELD™ for Dogs** can kill biting and chewing lice for up to a month. Apply monthly where lice control is consistently needed.

**CERTISHIELD™ for Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™ for Dogs** repels and prevents blood feeding by biting flies and mosquitoes for up to a month.

Wait at least 30 days before re-application of **CERTISHIELD™ for Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills and repels fleas, all stages of ticks, mosquitoes, biting flies, and chewing lice. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

**PESTICIDE STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL. If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL. If empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**How Supplied**

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 8 weeks or older and 11-22.9 lbs., medium dogs 23-44.9 lbs., large dogs 45-88.9 lbs., and extra-large dogs 89-132 lbs.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

Call: 1-800-660-1842,

Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-8

**Merial Limited**

3239 Satellite Blvd.

Duluth, GA 30096-4640, USA

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## (COMPLIANCE CARD)

## (FRONT)

See other side for more

**CERTISHIELD™ for dogs**

Some tips and other information:

DO NOT USE ON CATS.

To successfully control fleas, ticks, chewing lice, mosquitoes, biting flies and sarcoptic mange mites, all dogs must be treated with their own dose of **CERTISHIELD™**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **CERTISHIELD™** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Tick  
pictogramPipette  
pictogramAdult flea  
pictogramChewing lice  
pictogramMosquito  
pictogramBiting fly  
pictogram

## (BACK)

Calendar reminder stickers

Do not use on  
cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTISHIELD™**.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months  
Use all 6 stickers

-----  
3 months

5 stickers that read "Apply  
**CERTISHIELD™**", with the 6<sup>th</sup> sticker  
"Re-purchase **CERTISHIELD™**"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit [www.CERTISHIELD.com](http://www.CERTISHIELD.com).

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(LABEL ON INDIVIDUAL APPLICATOR)

**CERTISHIELD™ for Dogs**

6.01% fipronil  
44.88% Permethrin

ONLY for dogs & puppies (8 weeks or older and 11-22.9 lbs.)  
(23-44.9 lbs.)(45-88.9 lbs.)(89-132 lbs.)

EPA Reg. No. 65331-8

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on cats pictogram
---------------------------------

(LABEL ON BLISTER PACK)

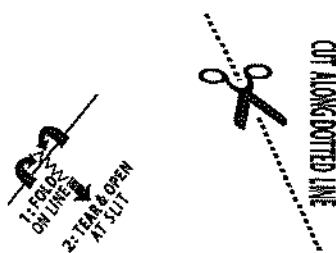
**CERTISHIELD™ for Dogs**

(0.034 fl. oz.)  
(0.068 fl. oz.)  
(0.135 fl. oz.)  
(0.203 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(DOG 22.9)(DOG 44.9)(DOG 88.9)(DOG 132)

Lot No.



**Alternate marketing text for carton or insert**

**CERTISHIELD™ for dogs** [starts rapidly killing fleas and ticks within 6 hours providing a convenient, effective treatment for fleas and ticks]. **CERTISHIELD™** kills and repels fleas, mosquitoes, biting flies, and kills chewing lice; ONLY for (dogs and puppies 8 weeks or older and 11-22.9 lbs.)(dogs weighing 23 – 44.9 lbs.)(dogs weighing 45 – 88.9 lbs.)(dogs weighing 89 – 132 lbs.).

**[Multiple Infestations]**

- Starts rapidly killing fleas (in) (as little as) (6 hours), and kills ticks including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks, mosquitoes and biting flies
- Repels and kills mosquitoes for up to four weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(Controls) existing infestations and prevents re-infestations of fleas and ticks
- Fast-acting, starts killing fleas (in)(as little as) (6 hours)
- Long-lasting for (1 month against ticks)(and)(3 months against fleas)
- Re-infestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month or longer
- After application, **CERTISHIELD™** spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, biting flies and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, mosquitoes, biting flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy, fast, effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, **CERTISHIELD™** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas)(of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of) flea(s)(infestations), (ticks), (mosquitoes), (biting flies), (and chewing lice)
- **CERTISHIELD™** uses (different)(multiple) modes of action to kill (ticks)(fleas)(mosquitoes)(chewing lice)(sarcoptic mange mites)(biting flies)
- For convenient, quick-acting, long-lasting control of fleas, ticks, mosquitoes and lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs repels and kills fleas, ticks and mosquitoes, kills (biting, chewing) lice, aids in control of sarcoptic mange mites and repels (and inhibits blood feeding) biting flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and lice; repel (against) biting flies, and repels and kills mosquitoes.
- Kills fleas, ticks, lice, and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- For the control and prevention of flea [and lice] infestations
- Flea, tick, (biting and chewing) lice infestations can be controlled with monthly applications of **CERTISHIELD™** for dogs.
- Biting flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas, ticks and mosquitoes
- Kills fleas, ticks and mosquitoes for (up to) one month
- Monthly application is recommended for control and prevention of fleas, ticks and mosquitoes

- Long lasting flea, tick and mosquito control for your pet
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas, ticks, mosquitoes, and lice on dogs and puppies 8 weeks of age and older
- Kills fleas, ticks, mosquitoes, lice, and aids in control of sarcoptic mange mites
- Kills and repels fleas, ticks, and mosquitoes.

#### [Fleas]

- Prevents fleas on treated dogs from infesting your home
- Kills fleas on dogs within (in) (as little as) (6 hour) and continues to prevent infestations for a month
- Kills fleas (before they lay eggs) (that may transmit bartonellosis and tapeworm disease)
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs within (6 hours).
- Re-infesting fleas are killed within (6 hours) with protection against further flea infestation lasting at least four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs within (6 hours) and continues to prevent infestations for a month.
- Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment
- May reduce the incidence of flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **CERTISHIELD™** rapidly kills fleas and may reduce the incidence of FAD
- **CERTISHIELD™** is useful for dogs susceptible to flea allergy dermatitis (FAD)
- Regular use of **CERTISHIELD™** breaks the flea life cycle
- Kills (newly emerged) fleas (before they lay eggs) for up to 12 weeks
- **CERTISHIELD™** for dogs can kill adult fleas in 6 hours (and lasts) for (up to) 12 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm infestations)
- Kills fleas (within 6 hours) that may transmit bartonellosis and tularemia
- Acts to kill fleas that may transmit bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) (or) (flea-bite anemia)
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- **CERTISHIELD™** for dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- Kills adult fleas for up to 3 months (12 weeks)
- Kills fleas
- Easy to apply, control of (for) fleas that lasts up to 3 months (12 weeks)
- **CERTISHIELD™** for dogs kills fleas on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 8 weeks of age and older

- One application prevents further flea infestations for up to (12 weeks) ([three] months)
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Provides ongoing protection against fleas
- Stops existing flea infestations by (rapidly) killing adult fleas
- Kills fleas before they lay eggs
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with **CERTISHIELD™** rapidly kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity
- Use flea [prevention] [protection] year-round

#### [Ticks]

- Kills all stages of ticks infesting dogs
- (Rapidly)(kills)(ticks)(which may cause)(which may transmit) Lyme disease, (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness)
- Kills ticks for (up to)(at least) 4 weeks
- **CERTISHIELD™** for dogs rapidly kills all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks, and Lone Star ticks
- Kills and repels ticks
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and heartworm disease.
- **Ticks: CERTISHIELD™** for dogs can kill ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks and Lone Star ticks (that may transmit ehrlichiosis) for up to one month (4 weeks)
- Kills Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills *Amblyomma americanum* (Lone Star ticks) for 4 weeks (for up to one month).
- Monthly application against ticks

## [Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to (28 days)(four weeks) (a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) biting flies and mosquitoes for (up to) 4 weeks (a [one] month)
- Repels and prevents blood-feeding by biting flies and mosquitoes for up (one) a month
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome )(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may be (a) vector(s) of heartworm (*Dirofilaria immitis*) for one month
- Repels and prevents blood-feeding by biting flies

## [Lice and Sarcoptic mange mites]

- (For treatment of)(Treats and controls)(Provides effective control of)(For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations)
- Kills chewing lice
- Lice: **CERTISHIELD™** for dogs can kill biting and chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (**CERTISHIELD™** for dogs) aids in (the) control of sarcoptic mange mites (that may cause sarcoptic mange)
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations (that may cause sarcoptic mange).
- (When applied monthly,) **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestations
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of sarcoptic mange mites
- Eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice (infestations)
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of (infestations with) [(biting) (chewing)] lice

## [Miscellaneous]

- **CERTISHIELD™** is waterproof and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- Convenient topical treatment for dogs who enjoy the outdoors
- (Convenient)(to use)(Easy to apply) spot-on application
- Persistent (sustained) efficacy through 30 days
- Protects for (at least) one month
- Convenient (easy to apply) topical treatment (with [patented] applicator)(that allows application down to the skin)
- (Patented) applicator (trademark) for easy application directly to the skin
- Quick-drying
- For easy and convenient application, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (8 weeks old or older) and 11-22.9 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 23-44.9 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 45-88.9 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 89-132 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application
- Guaranteed effective for (at least) one month
- New (combination)(formula for your dog(s))(first six months)
- Non-greasy
- (Formulated) for dogs that (enjoy)(love) the outdoors
- Waterproof
- Convenient to use
- (1)(3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml)
- (1)(3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.)
- (1)(3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (1)(3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml])
- (1)(3)(6) applicator(s)
- (1)(3)(6) monthly dose(s) [application(s)]
- (1)(3)(6) applicator(s)
- This product is only for use on dogs and puppies (8 weeks or older and 11-22.9 lbs.)(weighing 23 to 44.9 lbs.)(weighing 45 to 88.9 lbs.)(weighing 89 to 132 lbs.)
- Easy and convenient application(s)
- Stops existing infestations and prevents establishment of new infestations
- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- **CERTISHIELD™** is brought to you by the makers of FRONTLINE®
- Quick drying, non-greasy
- (Convenient) (to use) Easy (to apply) spot-on (topical) application
- No noticeable odors
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for you and your our pet
- Convenient, easy to apply topical solution
- Starts working by (on) contact
- (In) child-resistant packaging
- Convenient (to use), easy to apply (topical solution)
- Waterproof (remains effective after bathing and swimming) for up to four weeks (a month) (one month)
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight

- Remains effective even after bathing (and swimming)
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog (or puppy)
- Picture or illustration of the Merial logo
- Picture or illustration of the primary package (applicators)



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Merial Limited/65331-8	2. EPA Product Manager Richard Gebkin	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CERTISHIELD for dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code)  Merial Limited 3239 Satellite Blvd., Duluth, GA 30096  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of new acute toxicity studies for CERTISHIELD and an updated Data Matrix

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Printed _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Director, RA NPD	Telephone No. (Include Area Code) 678-638-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, RA NPD	
4. Typed Name Timothy A. Dotson	5. Date 12/21/12	

Timothy A. Dotson  
Director  
Regulatory Affairs US  
Tel: 678-638-3713  
Fax: 678-638-3715



3239 Satellite Blvd.  
Duluth, GA 30096  
Tel: 678 638 3000

December 21, 2012

Mr. Richard Gebken  
Registration Division  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**SUBJECT:** CERTISHIELD™ for dogs, EPA Reg. No. 65331-8  
Submission of New Acute Toxicity Studies and Updated Data Matrix

Dear Mr. Gebken:

Merial is hereby submitting new acute toxicity studies on the final formulation for CERTISHIELD™ for dogs, EPA Reg. 65331-8, for reevaluation of the labeling precautionary statements. Also, following a phone conversation with Marion Johnson on 18Dec12, we are submitting an alternate Data Matrix which cites data that are not exclusive-use data, and aside from a single study, are non-compensable. We are citing both efficacy and companion animal safety studies, and providing a rationale for "bridging" the individual companion animal safety studies conducted with Frontline (fipronil) and the ones conducted with permethrin. We are also citing Frontline studies for efficacy claims related to fipronil (adulticidal claims), and permethrin studies for efficacy claims relating to permethrin, e.g. repellency. Merial anticipates that any labeling changes required based on the evaluation of the new acute toxicity studies will be undertaken during this review period, with submission of labeling at a later date.

Volume 1 of this submission includes a cover letter, copy of the Application form (8570-1) and PRIA check, Data Certification form, and new Data Matrix. Volume 2 contains the Transmittal Document. Volume 3 contains the justification for bridging fipronil and permethrin studies. Three copies of each final study report are also included.

Merial anticipates that this submission will have PRIA category R340, AMENDMENT REQUIRING DATA REVIEW WITHIN RD (E.G., CHANGES TO PRECAUTIONARY LABEL STATEMENTS). This category provides for a 4-month statutory review time. A fee of \$3,617 is being remitted now in the form of a check payable to the US EPA. A copy of the check is included in this submission.

Thank you for your assistance in this matter. Please call me at 678-638-3713 (email at [Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson  
Director  
Regulatory Affairs NP US

www.merial.com



## TRANSMITTAL DOCUMENT

**Submitter:** Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640

**Regulatory Action:** Submission of new Acute Toxicity studies and an updated Data Matrix for EPA Reg. No. 65331-8

**Transmittal Date:** December 21, 2012

### List of Submitted Volumes:

VOLUME	Guideline	TITLE	MRID NO.
1 of 8	NA	Administrative Materials	
2 of 8	NA	Transmittal Document	
3 of 8	NA	Justification for Bridging Companion Animal Safety and Effectiveness Data for Fipronil and Permethrin	49027301
4 of 8	870.1100	ML-3,141,301: Acute Oral Toxicity Study in the Rat	49027302
5 of 8	870.1200	ML-3,141,301: Primary Dermal Irritation Study in Rabbits	49027303
6 of 8	870.2400	ML-3,141,301: Primary Eye Irritation Study in Rabbits	49027304
7 of 8	870.2500	ML-3,141,301: Acute Dermal Toxicity Study in Rats	49027305
8 of 8	870.2600	Delayed Contact Hypersensitivity in Hartley Guinea Pigs (Buehler Method) with ML-3,141,301	49027306

Company Official: Timothy A. Dotson  
Name

 12/21/12  
Signature/Date

Company Name: Merial Limited

Company Contact: Timothy A. Dotson 678-638-3713  
Name Phone

Email: timothy.dotson@merial.com



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	EPA Registration Number/File Symbol 65331-8
Active Ingredient(s) and/or representative test compound(s) Fipronil + Permethrin	Date December 21, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, non-food use	Product Name CERTISHIELD for dogs

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title


Dec. 21, 2012

Timothy A. Dotson, Director

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 65331-8	Page 1 of 8	
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Flpronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	PRODUCT IDENTITY AND COMPOSITION	48638301	MERIAL	OWN	
830.1600	DESCRIPTION OF MATERIALS USED TO PRODUCE THE PRODUCT	48638302	MERIAL	OWN	
830.1620	DESCRIPTION OF PRODUCTION PROCESS	48638303	MERIAL	OWN	
830.1650	DESCRIPTION OF FORMULATION PROCESS	48638302	MERIAL	OWN	
830.1670	DISCUSSION OF FORMATION OF IMPURITIES	48638301	MERIAL	OWN	
830.1700	PRELIMINARY ANALYSIS	48638303	MERIAL	OWN	
830.1750	CERTIFIED LIMITS	48638301	MERIAL	OWN	
830.1800	ENFORCEMENT ANALYTICAL METHOD	48638303	MERIAL	OWN	
830.1900	SUBMITTAL OF SAMPLES				UPON REQUEST
830.6302	COLOR	ADMIN	MERIAL	OWN	
830.6303	PHYSICAL STATE	ADMIN	MERIAL	OWN	
830.6304	ODOR	ADMIN	MERIAL	OWN	
830.6313	STABILITY TO NORMAL AND ELEVATED TEMP, METALS AND METAL IONS	48638303	MERIAL	OWN	
830.6314	OXIDATION/REDUCTION: CHEMICAL COMPATIBILITY	48638303	MERIAL	OWN	
830.6315	FLAMMABILITY	48638303	MERIAL	OWN	
Signature 			Name and Title Timothy A. Dotson, Director, Reg. Affairs US		Date 12/21/12

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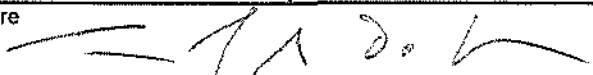
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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 65331-8	Page 2 of 8	
Applicant's/Registrant's Name & Address  Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			Product  CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	EXPLODABILITY	48638303	MERIAL	OWN	
830.6317	STORAGE STABILITY	48638303	MERIAL	OWN	
830.6319	MISCIBILITY	48638303	MERIAL	OWN	
830.6320	CORROSION CHARACTERISTICS	48638303	MERIAL	OWN	
830.6321	DIELECTRIC BREAKDOWN VOLTAGE	48638303	MERIAL	OWN	
830.7000	pH	ADMIN	MERIAL	OWN	
830.7050	UV/VISIBLE LIGHT ABSORPTION	48638303	MERIAL	OWN	
830.7100	VISCOSITY	ADMIN	MERIAL	OWN	
830.7200	MELTING POINT/MELTING RANGE	48638303	MERIAL	OWN	
830.7220	BOILING POINT/BOILING RANGE	48638303	MERIAL	OWN	
830.7300	DENSITY/RELATIVE DENSITY/BULK DENSITY	ADMIN	MERIAL	OWN	
830.7370	DISSOCIATION CONSTANTS IN WATER	48638303	MERIAL	OWN	
830.7520	PARTICLE SIZE, FIBER LENGTH, AND DIAMETER DISTRIBUTION	48638303	MERIAL	OWN	
830.7550 830.7560 830.7570	PARTITION COEFFICIENT (n-OCTANOL/WATER)	48638303	MERIAL	OWN	
Signature 			Name and Title Timothy A. Dotson, Director, Reg. Affairs US		Date 12/21/12

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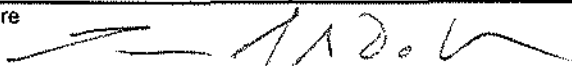
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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 65331-8	Page 3 of 8	
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			Product CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840 830.7860	WATER SOLUBILITY	48638303	MERIAL	OWN	
830.7950	VAPOR PRESSURE	48638303	MERIAL	OWN	
NOT APPLICABLE	RATIONALE FOR WAIVER REQUESTS	48638303	MERIAL	OWN	
Signature 			Name and Title Timothy A. Dotson, Director, Reg. Affairs US		Date 12/21/12

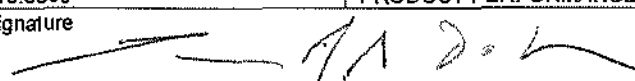
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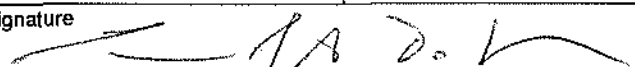
Date December 21, 2012			EPA Reg No./File Symbol 65331-8	Page 4 of 8	
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE – FLEAS/TICKS	43121114	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS/TICKS	43121115	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43121116	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43121119	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43121120	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43121121	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS/TICKS	43121122	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43444901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43577701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS/TICKS	43577712	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43577713	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	43951701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	44088901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	44942011	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	44942106	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45618501	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45620502	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45620503	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45628104	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45628105	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – FLEAS	45866901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – TICKS	43121117	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – BATHING	43121118	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – SARCOPTIC MANGE	45620504	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – SARCOPTIC MANGE	45620505	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – SARCOPTIC MANGE	45620506	MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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Date December 21, 2012			EPA Reg No./File Symbol 65331-8		Page 5 of 8
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE – MITES	43444901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MITES	43577701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MITES	43951701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MITES	45612701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MITES	45820503	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MITES	45866901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – LICE	45620501	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – LICE	45628101	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – LICE	45628102	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – LICE	45628103	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – LICE	45628201	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MOSQUITOES	45866902	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MOSQUITOES	46019202	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE – MOSQUITOES	46019201	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – FIPRONIL	43863802	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – FIPRONIL	44942104	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – FIPRONIL	45143901	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – FIPRONIL	45620507	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – FIPRONIL	45612702	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY – PERMETHRIN	41056906	COOPER'S ANIMAL HEALTH, INC.	OLD	
870.7200	COMPANION ANIMAL SAFETY – PERMETHRIN	41953201	COOPER'S ANIMAL HEALTH, INC.	OLD	
870.7200	COMPANION ANIMAL SAFETY – PERMETHRIN	43137201	HARTZ MOUNTAIN CORP.	OLD	
870.7200	COMPANION ANIMAL SAFETY – PERMETHRIN	43447101	HARTZ MOUNTAIN CORP.	OLD	
870.7200	COMPANION ANIMAL SAFETY – PERMETHRIN	43396408	ECTO DEVELOPMENT CORP.	OLD	
810.3300	COMPANION ANIMAL SAFETY – PERMETHRIN	43612601	ECTO DEVELOPMENT CORP.	OLD	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE	41038803	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43137202	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	41038802	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43137203	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	41683903	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43111607	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43398409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE - BITING FLY	46978901	BAYER HEALTHCARE L.L.C.	PAY	
810.3300	PRODUCT PERFORMANCE	42256901	COOPER'S ANIMAL HEALTH, INC.	OLD	
810.3300	PRODUCT PERFORMANCE	43396409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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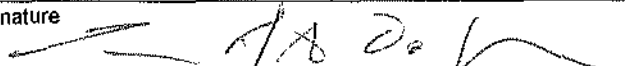
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Date December 21, 2012			EPA Reg No./File Symbol 65331-8		Page 7 of 7
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			Product CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	ACUTE ORAL TOXICITY – RAT	SUBMIT	MERIAL	OWN	
870.1200	ACUTE DERMAL TOXICITY – RAT	SUBMIT	MERIAL	OWN	
870.1300	ACUTE INHALATION TOXICITY				WAIVER
870.2400	PRIMARY EYE IRRITATION – RABBIT	SUBMIT	MERIAL	OWN	
870.2500	PRIMARY DERMAL IRRITATION – RABBIT	SUBMIT	MERIAL	OWN	
870.2600	DERMAL SENSITIZATION – GUINEA PIG	SUBMIT	MERIAL	OWN	
Signature 			Name and Title Timothy A. Dotson, Director, Reg. Affairs US		Date 12/21/12

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Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product CERTISHIELD™ for dogs	

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR PART 157, SUBPART B	CR/SAUE TESTING – 6x (XL)	49000901	MERIAL	OWN	
40 CFR PART 157, SUBPART B	CR/SAUE TESTING – 1x (L)	49000902	MERIAL	OWN	

Signature 	Name and Title Timothy A. Dotson, Director, Reg. Affairs US	Date 12/21/12
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OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

CHILD-RESISTANT PACKAGING REVIEW  
Technical Review Branch

IN 12/19/2012 OUT 3/4/2013

RD, TRB, Reviewed by Rosalind L. Gross 3/4/2013

EPA Reg. No. or File Symbol 65331-8

DP Barcode DP407731

Decision # 472190

EPA Petition or EUP No. \_\_\_\_\_

Date Division Received 11/20/2012

Type Product(s) Insecticide (flea product)

Data Accession No(s). 49000902 (1365-111), 49000901 (1365-110)

Product Mgr./Chemical Review Mgr/Contact Person RM 10 Driss Benmhend  
Division RD

Product Name(s) Tradename for Dogs

Company Name(s) Merial Ltd.

Submission Purpose Use previously reviewed CRP studies for EPA Reg No 65331-T in conjunction with these new studies to determine if they are adequate to support CRP certification for EPA Reg No 65331-8 as a 1x, 3x, and 6x blister (with 3 blisters connected to each other) for fill levels 1, 2, 4, and 6ml

Active Ingredient(s), PC code, & % Fipronil 6.01%  
Permethrin 44.88%

### **Summary of Findings**

A CRP certification dated February 20, 2013 (submitted via email) is acceptable. A label dated January 10, 2013 (via email) is acceptable in terms of using the same CRP directions for the 1x, 3x, and 6x blister package as were used for CRP testing EPA Reg. No. 65331-T and 65331-8. The CRP certification for EPA Reg. No. 65331-8 is based on 12 previously submitted and reviewed CRP studies for EPA Reg. No. 65331-T and 2 CRP studies for EPA Reg. No. 65331-8 that are reviewed in the Data Analysis and Conclusion section below.

**In conclusion, all the requirements for a 1x, 3x, and 6x blister card with 3 blisters connected to each other containing 4 different sizes (0.034 fl. oz. (1ml), 0.068 fl. oz. (2ml), 0.135 fl. oz. (4ml) and 0.203 fl. oz. (6ml)) have been met. It should be noted that these CRP requirements are being considered met on a combination of data for the specific package, supplemental data (12 studies for EPA Reg. No. 65331-T previously reviewed by the Agency), and bridging from the EPA Reg. No. 65331-T studies and the 2 studies for EPA Reg. No. 65331-8 that are reviewed in the Data Analysis and Conclusion section below.**

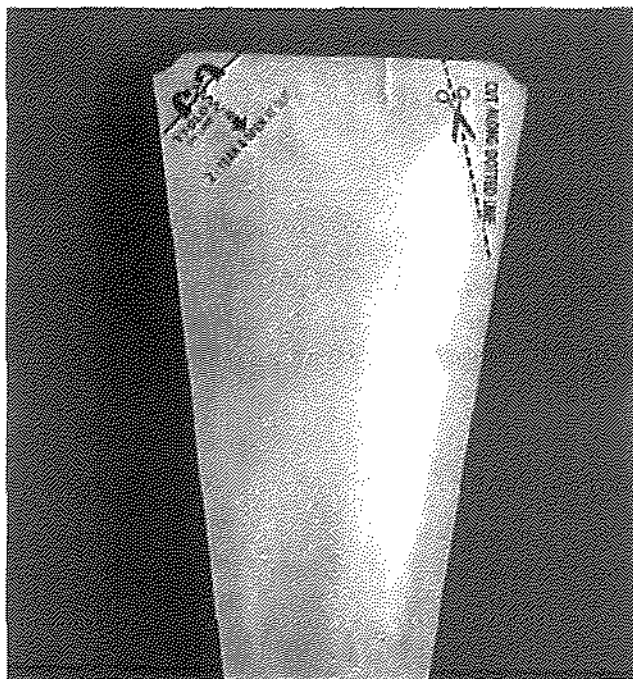
Any change in the CRP materials, design, size, fill volume, color of blisters, number of blisters per package, etc. may result in the requirement to submit additional/ supplemental data for these products to establish that they are CRP. Should any human experience and/or epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

### **Package**

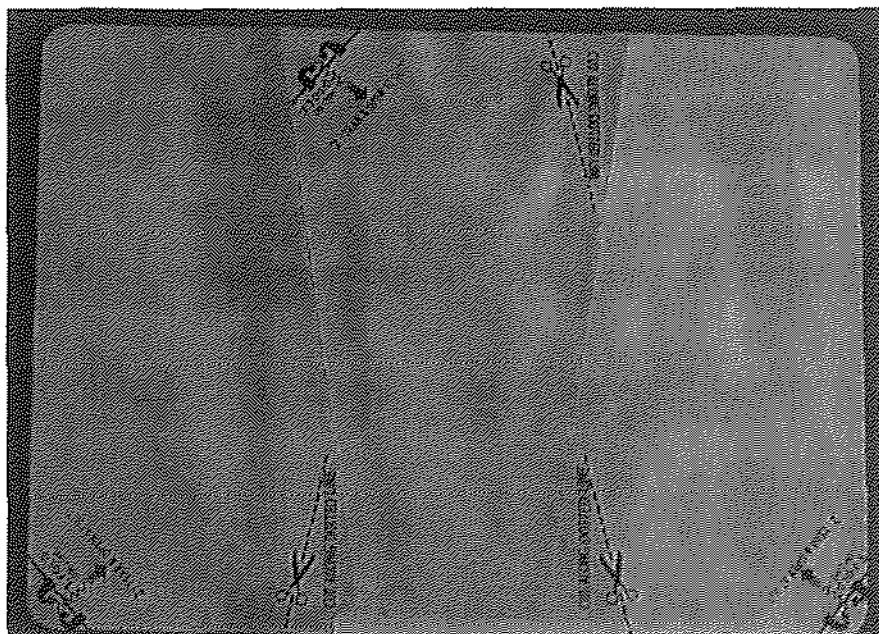
The package is a pipette enclosed in an opaque blister package. The pipette has four different fill levels, which are 0.034 fl. oz. (1ml), 0.068 fl. oz. (2ml), 0.135 fl. oz. (4ml), and 0.203 fl. oz. (6ml). The blister is the intended CRP. There are three different packages of the blisters. These are:

- A single blister (referred to as 1x);
- A three blister card, which has three individual blisters attached to each other (referred to as 3x);
- And two cards with three blisters attached to each other per card (referred to as 6x).

The front of the blister is aluminum colored and the back is white. The directions on the white side of each blister (the back) show a pair of scissors on a dotted line with the wording "CUT ALONG DOTTED LINE"; in the opposite corner there is a picture of a line with two arrows pointing to it and the wording "1: FOLD ON LINE", followed by an arrow pointing to number 2, "2: TEAR OPEN AT SLIT"; on the aluminum colored side of the blister in the same location (as the folding instructions on the back) there is a small slit. **The back of the single blister looks like:**



**The back of the three blister card looks like:**



In addition to the directions on the blister the Seniors were given the following directions during the Senior Adult Use Effectiveness (SAUE) test:

**The single blister –**

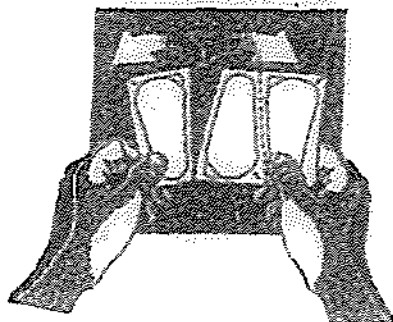
To open,  
use scissors to cut along dotted line of single blister,  
then pull apart foil and remove the applicator.

Or

fold on line at corner,  
tear and open at slit and remove the applicator.

**Three blister card and 2 three blister cards –**

**TO REMOVE APPLICATOR:**  
Prior to opening  
separate one blister by tearing along perforation.



To open,  
use scissors to cut along dotted line of single blister,  
then pull apart foil and remove the applicator.

Or

fold on line at corner,  
tear and open at slit and remove the applicator.

**Toxicity**

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals 28.5mg. Access to a toxic or harmful amt =  $28.5\text{mg} = 28.5\text{mg} \div [1150\text{mg/ml} \times 0.0601 \text{ Fipronil}] = 0.41\text{ml}$  for EPA Reg. No. 65331-8. Access to one applicator represents a failure for a child for all sizes equal to or greater than 0.41ml for EPA Reg. No. 65331-8.

**Failure**

For the purposes of CRP testing a child failure is access to one blister for all sizes. Access to one pipette is more than 28.5mg of Fipronil for all sizes.

A unit failure for the child test was defined as any partial or complete removal of the pipette from the blister, any pipette breakage resulting in leakage external to the blister irrespective of the extent to which the blister was opened, or access to the pipette or its contents in any fashion.

A Senior Adult Use Effectiveness failure is the inability to access the pipette by the correct mechanism in the allotted time of 5 minutes for the first package or 1 minute for the second package; cutting into an additional blister.

### Company Data

The Company submitted (via email) a CRP certification dated February 20, 2013 and a label dated January 10, 2013 using the same CRP directions for the 1x, 3x, and 6x blister package as were used for EPA Reg. No. 65331-T. Two CRP studies for EPA Reg. No. 65331-8 were also submitted.

### Data Analysis and Conclusion

A CRP certification dated February 20, 2013 (submitted via email) is acceptable. A label dated January 10, 2013 (via email) is acceptable in terms of using the same CRP directions for the 1x, 3x, and 6x blister package as were used for CRP testing EPA Reg. No. 65331-T and 65331-8. The CRP certification for EPA Reg. No. 65331-8 is based on 12 previously submitted and reviewed CRP studies for EPA Reg. No. 65331-T and 2 CRP studies for EPA Reg. No. 65331-8.

**Child Resistant Effectiveness (CRE) study 6ml 6x (MRID 49000901 (1365-110))**– Each child received two cards of 3 blisters each connected to each other at the start of the test. Each blister contained a pipette with 6ml of water. A child failure was defined as access to 1 blister as the blister was the child-resistant feature. The 50 child test resulted in 1 failure, a 48 month old female. The study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

**Senior Adult Use Effectiveness Test (SAUE) study 6ml 6x (MRID 49000901 (1365-110))**– involved giving the test subjects 2 cards with 3 blisters each connected to each other for a 5 minute test period and a one minute test period. The test report was corrected to reflect that the test subjects received 2 cards with 3 blisters each connected to each other for a 5 minute test period and a one minute test period. There was one 70 year old male who failed to open package B. SAUE is 99%. The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).

**Child Resistant Effectiveness (CRE) study 4ml 1x (MRID 49000902 (1365-111))**– Each child received one blister at the start of the test. Each blister contained a pipette with 4ml of water. A child failure was defined as access to 1 blister as the blister was

the child-resistant feature. The 50 child test resulted in 2 failures, two 50 month old females. There were two age calculation errors - a 44 month old female was reported to be 43 months old and a 48 month old female was reported as 46 months old. These errors did not affect the results because in both cases the child remained in the same age group. The study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

**Senior Adult Use Effectiveness Test (SAUE) study 4ml 1x (MRID 49000902 (1365-111))**— involved giving the test subjects one blister for a 5 minute test period and one blister for a one minute test period. There were two failures, a 59 year old female and a 65 year old female failed to open package B. SAUE is 98%. The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).

In conclusion, all the requirements for a 1x, 3x, and 6x blister card with 3 blisters connected to each other containing 4 different sizes (0.034 fl. oz. (1ml), 0.068 fl. oz. (2ml), 0.135 fl. oz. (4ml) and 0.203 fl. oz. (6ml)) have been met. It should be noted that these CRP requirements are being considered met on a combination of data for the specific package, supplemental data (12 studies for EPA Reg. No. 65331-T previously reviewed by the Agency), and bridging from the EPA Reg. No. 65331-T studies and the 2 studies<sup>1</sup> for EPA Reg. No. 65331-8 that are reviewed herein. For the results of the 12 studies previously reviewed see MRID 479142-42, 479142-43, 479142-44, 479142-45, 479142-46, 479142-47, 479142-48, 479142-49, 479142-50, 479142-51, 479142-52, and 479142-53 in review by Rosalind L. Gross October 18, 2010 [DP 372051, EPA Reg. No. 65331-T] and MRID 48310601, 48310602, 48310603, 48310604, 48310605, and 48310606 in review by Rosalind L. Gross December 23, 2010 [DP 384262 and 384698 EPA Reg. No. 65331-T].

Any change in the CRP materials, design, size, fill volume, color of blisters, number of blisters per package, etc. may result in the requirement to submit additional/ supplemental data for these products to establish that they are CRP. Should any human experience and/or epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

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<sup>1</sup> The 4ml study was based on the lowest CRE for EPA Reg. No. 65331-T and the 6ml was based on the lowest SAUE for EPA Reg. No. 65331-T. The rationale being if the lowest CRE and SAUE sizes for EPA Reg. No. 65331-T are high passes in a similar package size for EPA Reg. No. 65331-8 the remaining fill sizes and combinations as 1x, 3x, and 6x for EPA Reg. No. 65331-8 should also be passes of 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

02/APR/2013

MEMORANDUM: Acute Toxicity Review for Tradename for Dogs

Subject: Name of Pesticide Product: Tradename for Dogs  
EPA Reg. No. 65331-8  
DP Barcode: D409349  
Decision No.: 475004  
Action Code: R340  
PC Codes: 109701 Permethrin  
129121 Fipronil

From: Tracy Keigwin, Biologist  
Technical Review Branch  
Registration Division (7505P)

*May Keigwin*  
*Byron T. B...*  
*April - 2 - 2013*

To: Richard Gebken, RM 10  
Insecticide Branch  
Registration Division (7505P)

Applicant: Merial Ltd.  
3239 Satellite Blvd  
Duluth, GA 30096

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fipronil	6.01
Permethrin	44.88
<u>Other Ingredient(s):</u>	<u>49.11</u>

Total: 100.00%

**ACTION REQUESTED:** The Risk Manager requests a review of acute toxicity studies (MRIDs 49027302 (870.1100), 49027305 (870.1200), 49027304 (870.2400), 49027303 (870.2500), and 49027306 (870.2600) submitted in support of EPA Reg. No. 65331-8, Tradename for Dogs. EPA Reg. No. 65331-8 contains 6.01% Fipronil and 44.88% Permethrin and is for the control of fleas, ticks, lice, biting flies and mosquitos in dogs and puppies meeting the age and weight requirements as stated on the product label. The registrant has been challenged with a petition to deny due to their previous citation of exclusive use data. In response, Merial has submitted a revised data matrix which cites data (with the exception of one study) that the registrant states are not compensable. Note that the need for an acute inhalation toxicity study was previously waived (Backus 27/MAR/2012).

**GLP:** All studies were conducted in accordance with GLP.

**DEFICIENCIES:**

Overall – The recorded name of the test substance does not match the name on the product label, or the name on the CSF. The certificate of analysis does not provide the chemical or common name of the active ingredients in the test substance. While the internal names of the active ingredients approximately match the active ingredient label claim, it cannot be determined definitively that the test substance is the same as the proposed product. The registrant has not responded to a request for verification.

Acute oral toxicity study (MRID 49027302): The temperature in the animal room was outside the protocol limits of 19 to 25°C (recorded range was 14 to 26°C) Relative humidity was outside the protocol limits of 30 to 70% (recorded range 18% to 70%). The temperature of the room where the test substance was stored was unrecorded from April 18 2012 – April 25 2012. Adjacent rooms during that time had temperatures within protocol limits (15-30°C). TRB concludes that these deviations did not impact study results.

Acute dermal toxicity study (MRID 49027305): The temperature in the animal room was outside the protocol limits of 19 to 25°C (recorded range was 14 to 26°C). The relative humidity was outside the protocol limits of 30 to 70% (recorded range 18% to 70%). The temperature of the room where the test substance was stored was unrecorded from April 18 2012 – April 25 2012. Adjacent rooms during that time had temperatures within protocol limits (15-30°C). The age of the animals used in the study was outside the range stated in the protocol (protocol range 8-12 weeks, test used animals 7-8 weeks) however, the bodyweight was within protocol range. There was no mortality and morbidity check made on study day 1; however there was no mortality observed during the study. TRB concludes that these deviations did not impact the study results.

Primary eye irritation study (MRID 49027304): The relative humidity in the animal room was outside the protocol limits of 30 to 70% (recorded high 78%) and unrecorded for slightly less than 24 hours June 6, 2012 – June 7, 2012. The temperature of the room where the test substance was stored was unrecorded from April 18 2012 - April 25 2012. Adjacent rooms during that time had temperatures within protocol limits (15-30°C). The 72 hour observation to the test animal

was made at 73 hours and 42 minutes. TRB concludes that these deviations did not impact the study results.

Only one test animal was used in the primary eye irritation study. EPA Guideline 870.2400 states that the use of one animal is acceptable when a test substance is likely to be severely irritating. The test substance did elicit a strong reaction (grade 3-4 chemosis from the 1 hour observation through the day 5 observation), however, all positive results cleared within 7 days suggesting category 3 for primary eye irritation. Two additional animals should have been tested; because only one animal was used the test material is assigned to toxicity category II.

Primary dermal irritation study (MRID 49027303): The relative humidity was outside the protocol limits of 30 to 70% (recorded range 44 to 82%). The temperature of the room where the test substance was stored was unrecorded from April 18 2012 - April 25 2012. Adjacent rooms during that time had temperatures within protocol limits (15-30°C). The age of the test animals used in the study was outside the range stated in the protocol (protocol range 12-18 weeks, test animals used were 10 weeks) however, the bodyweight was within protocol range. Dermal scores were not taken at times as specified in 870.2500. For the 3 minute site scores: the 24 hour observation was taken at 27 hours, the 48 hour observation was taken at 52 hours and 3 minutes, and the 72 hours observation was taken at 75 hours and 5 minutes. For the 60 minute site scores, the 24 hour observation was taken at 26 hours 16 minutes, the 48 hour observation was taken at 51 hours and the 72 hour observation was taken at 74 hours 2 minutes. Since EPA determines primary dermal irritation based on a 4 hour exposure period TRB does not believe these deviations impacted the study results.

Dermal sensitization study (MRID 49027306): The temperature in the animal room was outside the protocol limits of 18 to 26°C (recorded range was 14 to 26°C). The relative humidity was outside the protocol limits of 30 to 70% (recorded range 21 to 97%). The temperature of the room where the test substance was stored was unrecorded from April 18 2012 - April 25 2012. Adjacent rooms during that time had temperatures within protocol limits (15-30°C). The weight of two of the test animals was outside the range stated in the protocol (protocol range 250 to 500 grams; 2 animals were 507 and 508g) however the animals were within the protocol age range. On the positive control study scores of 3 were not reported to Calvert DLAM for consultation, however enough positive scores were recorded to confirm the validity of the positive control study. TRB concludes that these deviations did not impact the study results.

#### COMMENTS AND RECOMMENDATIONS:

1) The 6 submitted studies are acceptable but cannot at this time be used to support EPA Reg. No. 65331-8. The recorded name of the test substance does not match the product name on the label, or the name on the CSF. The certificate of analysis does not provide the chemical or common name of the active ingredient in the test substance. While the internal names of the active ingredients approximately match the active ingredient label claim, it cannot be determined definitively that the test substance is the same as the proposed product. The

acceptability of these studies to support EPA Reg. No. 65331-8 will be reevaluated when the registrant provides clarification of the test substance. If the test substance is different from the formulation listed on the Basic CSF (dated March 2, 2012) the registrant must provide the active and inert ingredients (and their concentrations) in the test substance or, if appropriate, the name of the registered product (if the studies were conducted on a different registered product).

With regard to the primary eye irritation study: The use of one animal is acceptable only when a test substance is suspected of being severely irritating. The irritation to the eye was significant from the 1 hour to day 6 observations and grade 1 redness and grade 1 chemosis persisted through study day 8. While TRB does not believe that a test with two additional animals would have resulted in a category I rating, there is the likelihood that the results from two additional animals would have placed the test substance in category II. If the registrant disagrees with this classification they may repeat the study with EPA Reg. No. 65331-8 as the test substance.

**LABELING:** TRB will provide precautionary labeling when the test substance has been verified and/or the appropriate studies have been submitted or cited.

Reviewer: Tracy Keigwin  
Risk Manager (EPA): 10

Date: April 2, 2013

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies submitted for in support of EPA Reg. No. 65331-8, Tradename for Dogs:

<b>1. DP BARCODE:</b> 409349				
<b>2. PC CODES:</b> 109701 (Permethrin) and 129121 (Fipronil)				
<b>3. CURRENT DATE:</b> April 2, 2013				
<b>4. TEST MATERIAL:</b> ML-3,141,301 (Experimental ML-3, 141,301 503J 001 Solution for Rats -or- Experimental ML-3, 141,301 503J 001 Solution for Rabbits -or- Experimental ML-3, 141,301 503J 001 Solution for Guinea Pigs; Lot/Batch No.: ML-3,141,301 503J 001; Purity: ML-2,095,988 (6.01% w/w) and ML-3,145,140 (44.88% w/w) Also known as ML-3,141,301 Topical Solution for Dogs; Specific gravity: 1.1235 g/mL; colorless liquid				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Calvert Laboratories, Inc. (Scott Township, PA) Calvert Study #0406RM52.005 Merial Study No.: PR&D 0254801 06/December/2012 OCSPP 870.1100; OECD 425	49027302	LD <sub>50</sub> Females > 1000 mg/kg bw All 5 animals survived to study termination. 1 female was initially dosed at 1000 mg/kg. When no mortality was observed 4 additional females were dosed at 1000 mg/kg. Clinical abnormalities observed during the study included abnormal gait and stance, body quivering, decreased activity, piloerection and/or bright yellow urine. All test animals appeared normal on days 4-15 of the study. There was no effect on body weight gain. No gross abnormalities observed at necropsy.	III	A
Acute dermal toxicity/rat Calvert Laboratories, Inc. (Scott Township, PA) Calvert Study #0422RM52.005 Merial Study No.: PR&D 02549 (0254901) 06/December/2012 OCSPP 870.1200; OECD 402	49027305	LD <sub>50</sub> > 5000 mg/kg bw (both sexes and combined). All animals survived. On study day 2 4/5 females exhibited bright yellow urine and/or staining of the lower ventral area, persisting in 1/5 through study day 8. All animals appeared normal from study day 9 through study termination (day 15). No gross abnormalities observed at necropsy.	IV	A

<p>Primary eye irritation / rabbit Calvert Laboratories, Inc. (Scott Township, PA) Calvert Study #0421LM52.004 Merial Study No.: PR&amp;D 02551 (0255101) 06/December/2012 OCSP 870.2400; OECD 405</p>	49027304	<p>One animal treated. No corneal opacity was observed during the study. Iritis was observed at the one hour observation, resolving by day 7. Grade 2 redness was observed from the 72 hour observation through the day 6 observation. Grades 2-4 chemosis was observed from the 1 hour observation through day 6. All scores zero at day 15. MMTS = 21 at 1 hour, 72 hours and on day 5.</p> <p>*Although study results suggest Category III, TRB is categorizing MRID 49027304 as category II. Details are provided on page two under "Comments and Recommendations"</p>	II*	A
<p>Primary dermal irritation / rabbit Calvert Laboratories, Inc. (Scott Township, PA) Calvert Study #0420LM52.005 Merial Study No.: PR&amp;D 02550 (0255001) 06/December/2012 OCSP 870.2500; OECD 404</p>	49027303	<p>Three exposure periods: 3 minutes, 60 minutes and 4 hours.</p> <p>3 minute exposure: Grade 1-3 erythema was observed from the day 2 through day 8 observations, resolving within 9 days. Grade 1 edema was observed from the day 2 observation through the day 5 observation, resolving within 5 days. Desquamation was observed at the day 6 observation.</p> <p>60 minute exposure: Grade 1-2 erythema was observed from the day 2 through day 8 observations, resolving within 9 days. Grade 2 edema was observed from the day 4 through the day 5 observation, resolving within 6 days.</p>	III	A

		<p>Four hour exposure: PDII = 2.5 with a mean score at 72 hours = 3.67. Grade 0-3 erythema was observed in all animals (3/3) through study day 7, resolving by study day 8 in 2/3 and by day 9 in the remaining animal. Grade 0-2 edema was observed in all animals through the day 7 observation, resolving within 8 days. Desquamation was observed in 2/3 animals at the day 5 observation and in all animals at the day 6 observation, resolving in 2/3 animals within 8 days and within 9 days in the remaining animal. All scores zero by study day 9.</p>		
<p>Dermal sensitization (Buehler)/Guinea Pig Calvert Laboratories, Inc. (Scott Township, PA) Calvert Study #0424GM52.003 Merial Study No.: PR&amp;D 02724 (0272401) 06/December/2012 OCSPP 870.2600; OECD 406</p>	49027306	<p>Tested using Buehler method 20 test animals/10 controls Induction and challenge used undiluted test material. Following challenge, no positive dermal reactions were seen on any of the treated or naïve control animals at either time point. Appropriate positive control study (induction 0.3% (w/v) DNCB in 80% ethanol; challenge 0.2% DNCB in acetone) was provided. <i>Not</i> a sensitizer</p>	Neg	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

March 20, 2013

**MEMORANDUM:**

Subject: Name of Pesticide Product: TRADENAME FOR DOGS  
EPA Reg. No. /File Symbol: 65331-8  
DP Barcode: DP 409348  
Decision No.: 475004  
Action Code: R340  
PC Codes: 109701 (Permethrin: 44.88%)  
129121 (Fipronil: 6.01%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*March 20, 2013*

To: Richard Gebken RM 10  
Insecticide Branch  
Registration Division (7505P)

Registrant: MERIAL LIMITED

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
109701 Permethrin	44.88%
129121 Fipronil	6.01%
<u>Other Ingredient(s):</u>	<u>49.11%</u>
TOTAL	100.00%

**ACTION REQUESTED:** "The registrant has been challenged with a petition to deny from the me-too registrant (Virbac) for citing exclusive use data. Merial is providing information to remedy the data deficiencies in their current application since Virbac would not provide permission to utilize their data. Please review this package to determine if their CAS bridging argument is a valid argument for use to satisfy the CAS studies."

**BACKGROUND:**

The material received includes a document (MRID 49027301) titled: "Justification for Bridging Companion Animal Safety and Effectiveness Data for Fipronil and Permethrin." There is also a data matrix (dated 12/21/12) in which a number of citations are made to companion animal safety data for fipronil (MRIDs 43863802, 44942104, 45143901, 45620507 and 45612702) and permethrin (MRIDs 41056906, 41953201, 43137201, 43447101, 43396408 and 43612601). However, none of these studies was conducted on a formulation containing both fipronil and permethrin.

**COMMENTS AND RECOMMENDATIONS:**

1. The Agency does not generally accept bridging arguments for pet products to satisfy the companion animal safety study data requirement. As stated in the 870.7200 Guidelines a companion animal safety study is conducted for the purpose of establishing an adequate margin of safety and not a NOEL of toxicity. The presence of two or more active ingredients in a formulation results in the potential for additive or synergistic toxicity. This could include (but would not necessarily be limited to) effects involving dermal irritation, behavior, food consumption, body weight, and hematology and clinical chemistry parameters.
2. The only exception to this is when a registrant proposes addition of moderate amounts of S-methoprene or nylar to a pet care product formulation that has an adequate data base (including companion animal safety data). In this situation additional companion animal safety studies are not necessary because it has been established that these IGRs (insect growth regulators) have low toxicity to mammalian species.
3. TRB concludes that the companion animal safety study data requirements for 65331-8 (with the active ingredients fipronil and permethrin) cannot be satisfied by bridging from studies in which animals were not simultaneously exposed to both these active ingredients.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

**From:** Kevin Sweeney, Senior Entomologist

**Date:** April 30, 2013

**Subject:** PRODUCT PERFORMANCE DATA EVALUATION RECORD

**DP barcode:** 409353

**Decision no.:** 475004

**Submission no:** 930715

**Action code:** R340

**Product Name:** Tradename for Dogs

**EPA Reg. No or File Symbol:** 65331-8

**Formulation Type:** RTU spot-on for dogs

**Ingredients statement from the label with PC codes:** 6.01% fipronil (pc code 129121) and 44.88% permethrin (pc code 109701)

**Application rate:** spot-on based on number of vials per unit weight

**Use pattern:** dog spot-on

**OCSPP Guidelines:** 810.3300

**I. Action Requested:** Review cited efficacy data and amended product label.

**II. Background:** Registrant cited non-compensable efficacy data in lieu of previous citations that Virbac claims are exclusive use data.

**III. Study Reviews**

**Fipronil efficacy data:**

**Merial:** 43212114, 43212115, 43212116, 43212119, 43212120, 43212121, 43212122, 43444901, 435777701, 43577712, 43577713, 43951701, 44088901, 44942011, 44942106, 45618501, 45620502, 45620503, 45628104, 45628105, 45866901, 43121117, 43121118, 45620504, 45620505, 45620506, 45612701, 45620503, 45620501, 45628102, 45628103, 45628201, 45866902, 46019202, 46019201

**Coopers' Animal Health:** 41038802, 41038803

**Hartz Mountain Corporation:** 431372202, 431372203, 43111607

**Ecto Development Corporation:** 43396409, 43396410, 41683903,  
**Wellmark:** 46006002,  
**Bayer:** 46978901

**Permethrin efficacy data:**

**Cooper's Animal Health:** 42256901  
**Ecto Development Corporation:** 43396409 and 43396410

The registrant was unable to cite Virbac product data as it is subject to exclusive use provisions. Those data were used to register EPA Reg. No. 9688-187, which has the same level of active ingredients as the subject product. Please find the DER from Clayton Myers attached.

**Conclusion:** Merial needs to generate product specific data or submit a justification for the use of the existing database for a product that is not similar to the Frontline products.

#### **IV. Entomologist's Recommendations:**

1. Merial needs to generate product specific data or submit a justification for the use of the existing database to satisfy their product specific efficacy. The new product is not similar to Merial's Frontline products, and since they are unable to cite Virbac's product specific data, they must provide product specific data or a detailed justification for supporting their product efficacy data requirement with the existing database.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

To: Bonaventure Akinlosotu

From: Clayton Myers, Entomologist

Date: November 8, 2011

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 391921  
Decision no.: 448350  
Submission no: 897940  
Action code: R310  
Product Name: Effitix Topical Solution for Dogs  
EPA Reg. No or File Symbol: 2382-RIT  
Formulation Type: Pet Spot-On  
Ingredients statement from the label with PC codes included: Permethrin, 44.88% PC: 109701; Fipronil, 6.01% PC: 129121

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m<sup>2</sup> or mg/cm<sup>2</sup> as appropriate): Rate not provided on label. States one bottle (sizes not listed in net contents) will treat a surface up to [360][500] square feet.

I. Action Requested: Data was submitted to support pest claims for a pet spot-on product.

II. Background: The registrant seeks to register a fipronil/permethrin combo spot-on product for control of fleas, ticks, and other pests on dogs. The registrant has submitted 9 studies to support efficacy claims, in addition to selective citations.

III. MRID Summaries: (Primary Review attached)

a. MRID 48510701: Efficacy Study Against Fleas (Ctenocephalides) on Dogs: Onset of Action.

1. GLP Study

2. A laboratory study was conducted to test the speed of effectiveness of a fipronil/permethrin combination product with equivalent concentrations as the submitted product (on a w/w % basis). Dogs were qualified for flea retention and allocated into 2 groups, a treatment and a control group (10 dogs each in the treated groups and 6 in the control group). Dogs were infested with fleas on day -6 and day -1. After treatment on day 0, dogs were kept in individual pens. Flea comb counts were conducted on day -5 and on day 0 at 2, 6, and 12 hours after treatment. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Mean flea reduction efficacy at 6 hours after treatment was 94.4% (88.6% if the regular arithmetic mean was used). Flea efficacy exceeded 99% by 12 hours after treatment.

4. The primary reviewer agrees that the study is adequate to support killing claims against fleas within 6 hours of treatment. The reviewer comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the

concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is acceptable and claims of killing fleas within 6 hours of treatment are adequately supported.

b. MRID 48467122: Efficacy Study Against *Rhipicephalus sanguineus* in Dogs: Duration of Action.

1. GLP Study

2. A laboratory study was conducted to test the efficacy and duration of control of Brown Dog Ticks on dogs for a fipronil/permethrin combination product with equivalent concentrations as the submitted product on a w/w % basis). Dogs were infested with adult ticks for the study. 6 dogs were placed in a treatment group and 6 others in a control group. Each dog received 50 ticks on day -6, and days 0, 7, 14, 21, 28, 35, 42, 29, 56, and 63. Tick counts and mortality assessment was conducted on day -4, 1, 2, 9, 16, 23, 30, 37, 44, 51, 58, and 65. The ticks were categorized as being alive or dead, and also in 3 subgroups: free, attached and unengorged, or attached and engorged. Ticks were counted and removed during the 48 h assessment. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Efficacy at 2 days after treatment was 86.6%, but efficacy then exceeded 90% after each subsequent reinfestation through day 51. The study author states that efficacy should be adequately supported for 7 weeks after treatment.

4. The primary reviewer agrees that the study is adequate to support claims against BDT through 7 weeks after treatment. The reviewer comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is acceptable and claims of killing BDT are supported for 7 weeks after treatment.

c. MRID 48467123: Efficacy Study Against *Dermacentor variabilis* on Dogs: Duration of Action.

1. GLP Study

2. A laboratory study was conducted to test the efficacy and duration of control of American Dog Ticks on dogs for a fipronil/permethrin combination product with equivalent concentrations as the submitted product on a w/w % basis). Dogs were infested with adult ticks for the study. 6 dogs were placed in a treatment group and 6 others in a control group. Each dog received 50 ticks on day -6, and days 0, 7, 14, 21, 28, 35, 42, 29, 56, and 63. Tick counts and mortality assessment was conducted on day -4, 1, 2, 9, 16, 23, 30, 37, 44, 51, 58, and 65. The ticks were categorized as being alive or dead, and also in 3 subgroups: free, attached and unengorged, or attached and engorged. Ticks were counted and removed during the 48 h assessment. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Efficacy at 2 days after treatment was 49.4%, but efficacy then exceeded 90% after each subsequent reinfestation through day 44. The study author states that efficacy should be adequately supported for 6 weeks after treatment.

4. The primary reviewer agrees that the study is adequate to support claims against ADT through 6 weeks after treatment. The reviewer comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is acceptable and claims of killing ADT are supported for 6 weeks after treatment.

d. MRID 48467124: Efficacy Study Against the Brown Dog Tick (*Rhipicephalus sanguineus*) and the Cat Flea (*Ctenocephalides felis*) on Dogs: Effects of Shampooing and Periodic Water Immersions.

1. GLP Study

2. A laboratory study was conducted to to evaluate the efficacy and duration of control of a fipronil/permethrin combination product against fleas and ticks after shampooing and water immersion, in support of waterproof claims. 24 dogs were blocked within gender and weight groups in 6 blocks of 4 dogs in descending order of pre-treatment flea counts, and assigned to 3 treatment groups: Group 1 was a control group that was shampooed and water immersed, 6 dogs. Group 2 was treated with the test

substance, 6 dogs. Group 3 was treated with the test substance and shampooed, 6 dogs. Group 4 was treated with the test substance and water immersed, 6 dogs. Dogs were infested with fleas (100) on days -4, 0, 7, 14, 21, and 28. Dogs were also infested with ticks (50) on days -5, -1, 6, 13, 20, and 27. Shampooing occurred on day 12. Water immersion on days 12 and 26. Flea and Tick counts were conducted on days -2, 2, 9, 16, 23, and 30. For water immersion and shampooing, animals were rinsed using a shower head for 5 minutes at a flow rate of 2 gallons/minute. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Tick efficacy at 2 days was variable, but at days 9-30, tick efficacy exceeded 99% for all treatment groups, including dogs that were shampooed or water immersed. Flea efficacy exceeded 90% at 2 days, and was at 100% at days 9-10, for all treatment groups, including dogs that were shampooed or water immersed. The study author states that efficacy is adequately supported for fleas and ticks after water immersion and shampooing.

4. The primary reviewer agrees that the study is adequate to support claims against ticks and fleas through 1 month after treatment, with shampooing and water immersion. The reviewer comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is acceptable and claims of fleas and ticks for 1 month after treatment, with water immersion and shampooing, i.e., 'waterproof' claims.

- e. MRID 48467125: The Duration of Efficacy of a Single Application of 104.05 (Fipronil 6.7%, Permethrin 50%) Compared to a No Treatment Control Against Artificially Induced Infestations of Ticks (*Amblyoma americanum*) on Dogs.

1. GLP Study

2. A laboratory study was conducted to test the efficacy and duration of control of *Amblyoma americanum* on dogs for a fipronil/permethrin combination product with equivalent concentrations as the submitted product on a w/w % basis). Dogs were infested with adult ticks for the study. 6 dogs were placed in a treatment group and 6 others in a control group. Each dog received 50 ticks on day -7, and days 0, 7, 14, 21, 28, 35, and 42. Tick counts and mortality assessment was conducted on day -4, 1, 2, 9, 16, 23, 30, 37, and 44. The ticks were categorized as being alive or dead, and also in 3 subgroups: free, attached and unengorged, or attached and engorged. Ticks were counted and removed during the 48 h assessment. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Efficacy at 2 days after treatment was 70%, but efficacy then exceeded 90% after each subsequent reinfestation through day 23. Efficacy was 88% at day 37. The study author states that efficacy should be adequately supported for 23 days after treatment, with some residual control of ticks through 30 and 37 days.

4. The primary reviewer agrees that the study is adequate to support claims against BDT through 3 weeks after treatment, but that one month control claims were not adequately supported, as the 90% efficacy threshold was not met for day 30. The reviewer also comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is unacceptable and claims of killing *Amblyoma americana* for one month, but is partially acceptable and is adequate to support claims for 3 weeks after treatment.

- f. MRID 48467126: Duration of Efficacy of a Single Application of 104.05 (Fipronil 6.7% w/v, Permethrin 50% w/v) Compared to a No Treatment Control Against Artificially Induced Infestations of Ticks (*Ixodes scapularis*) on Dogs.

1. GLP Study

2. A laboratory study was conducted to test the efficacy and duration of control of Black Legged Ticks on dogs for a fipronil/permethrin combination product with equivalent concentrations as the submitted product on a w/w % basis). Dogs were infested with adult ticks for the study. 6 dogs were placed in a treatment group and 6 others in a control group. Each dog received 40 ticks on day -7, and with 50 ticks on days 0, 7, 14, 21, 28, 35, and 42, and with 35 ticks on day 49. Tick counts and mortality assessment was conducted

on day -5, 2, 9, 16, 23, 30, 37, 44 and 51, at 48 hours after infestation. The ticks were categorized as being alive or dead, and also in 3 subgroups: free, attached and unengorged, or attached and engorged. Ticks were counted and removed during the 48 h assessment. Efficacy calculations were based on geometric means and percent efficacy was calculated using Abbott's Formula.

3. Efficacy at 2 days after treatment was 94%, and efficacy then exceeded 90% after each subsequent reinfestation through day 37. The study author states that efficacy should be adequately supported for 37 days after treatment, with some residual control of ticks through 44 and 51 days.

4. The primary reviewer agrees that the study is adequate to support claims against BLT through 30 days after treatment. The reviewer also comments that the weight/volume 'concentrations' used in the study do not exactly match those on the submitted product CSF, but notes that another study validates the concentrations, when converted to a weight/weight ratio to calculate the active ingredient concentrations. This study is acceptable and one month claims against BLT are adequately supported.

g. MRID 48467127: Determination of a Combination of Fipronil and Permethrin in Topical Solution Against Mosquitoes (*Aedes aegypti*) on Dogs.

1. GLP Study

2. A laboratory study was conducted to test the efficacy of a fipronil/permethrin product against mosquitoes for repellence (preventing feeding) and killing of *A. aegypti*. Dogs were qualified as mosquito hosts, with dogs allowing a feeding rate of 40% were considered acceptable for the study. 12 dogs were randomly assigned into 2 groups, a treatment and control group. The product was applied on day 0. Dogs were exposed for 28-35 minutes to unfed female mosquitoes in exposure cages on days 1, 7, 14, 21/22, 28, and 35-37. Dogs were sedated during infestations. Afterwards, the mosquitoes were collected and dogs were removed from the exposure cages and returned to normal housing. At 50-90 minutes after exposure, dead and alive mosquitoes were counted. The mosquitoes were frozen and crushed to determine if a blood meal had been taken. Mortality was calculated for both feeding efficacy (repellence) and killing efficacy. Efficacy calculations were made using Abbott's Formula.

3. Short-haired dogs were more susceptible to mosquitoes than long hair dogs. The test product has a more effective repellence efficacy than killing efficacy. Killing efficacy never exceeded 59.5%. Repellence efficacy was 91.7% efficacy at 7 days after treatment.

4. The primary reviewer concludes that the study is not acceptable to support claims against mosquitoes, as no killing efficacy was demonstrated and repellence was only adequate at 7 days after application. The study is not acceptable to support any claims against mosquitoes.

h. MRID 48467128: Repellence Efficacy Study of 104.05 Against Ticks (*Dermacentor variabilis* and *Rhipicephalus sanguineus*) on Dogs Under Laboratory Conditions.

1. GLP Study

2. A laboratory study was conducted to evaluate the repellence of ticks for a fipronil/permethrin combination product. 12 dogs were used in the study, with 6 dogs given treatment and 6 dogs left as an untreated control group. Adult BDT and ADT were used in artificial infestations. Dogs were infested with 30 unfed ticks on day -6 (*R. sanguineus* only), and days 1, 2, 7, 14, 21, 22, and 28. Tick assessments were conducted on days 1, 2, 7, 14, 21, 22, and 28 at 3 hours after infestation/reinfestation. Tick counts with removal were conducted on days -5, 2, 4, 8, 15, 22, 23, and 29, 24 hours after the infestations. Ticks were categorized as being alive or killed and in 3 subgroups: free, attached and engorged, or attached and unengorged. Ticks found in the infestation chamber after removal of the dogs were categorized as live, moribund or dead. % mortality was calculated using Abbott's Formula.

3. BDT repellence efficacy was 90-95% for the 3 hour assessments through 14 days. Efficacy was 99% or greater for the 24 hour assessment through 29 days. For ADT, repellence efficacy was 90-97% for the 3 hour assessments through 22 days. Efficacy was 97% or greater for the 24 hour assessment through 29 days. The author concludes that repellence efficacy for ticks is supported through up to 29 days after treatment.

4. The primary reviewer concurs that basic tick repellence claims are supported for up to one month after application. The study is acceptable to support claims of tick repellence for up to one month.

- i. MRID 48467129: Summary of Efficacy Data for Effitix™ Topical Solution for Dogs End Use Product.

This MRID was a summary of selectively cited and submitted studies in support of label claims. The submission is supplemental.

- j. Selective Citations of 60 MRIDs from the fipronil and permethrin efficacy database including the following:

43121114, 43121115, 43121116, 43121119, 43121120, 43121121, 43121122, 43444901, 43577701, 43577712, 43577713, 43951701, 44088901, 44942011, 44942106, 45618501, 45620502, 45620503, 45628104, 45628105, 45866901, 43577712, 43121114, 43121115, 43121117, 43121122, 43121118, 45620504, 45620505, 45620506, 43444901, 43444901, 43577701, 43951701, 45612701, 45620503, 45866901, 45620501, 45618101, 45628102, 45628103, 45628201, 45866902, 46019202, 46019201, 41038802, 41038803, 43137202, 43137203, 43396409, 43396410, 46006002, 41683903, 43111607, 43396409, 43396410, 46978901, 42256901, 43396409, 43396410

These studies support efficacy claims (in various versions) against fleas, ticks, lice (chewing/biting), mites (aids in control of sarcoptic mange), mosquitoes, and repellence of biting flies.

Claims are not supported for sand flies, for killing/control of mites (only 'aids in control'), or sucking lice.

#### IV. RECOMMENDATIONS:

(1) Labeling:

- (a) *What pests and site/pest combinations may be added as follows to the label based on the submitted or cited data?*

Fleas: Killing within 6 hours and control for up to one month. Also repellence of fleas.

Ticks: Killing and controlling for up to one month. Also repellence of fleas.

Mosquitoes: Killing and controlling for up to one month, also repellence and prevention of blood feeding for up to one month

Biting Flies: Repellence

Lice (chewing/biting): Killing and controlling for up to one month

Mites: Aids in control of sarcoptic mange/mites that may cause sarcoptic mange, etc.

- (b) *What pests and site/pest combinations must be removed from the label?*

Any and all claims against sandflies

Any claims of control of fleas or ticks beyond one month (given that waterproof claims are included)

Killing/controlling claims against mites (only aids in control is supported)

Any and all claims against 'sucking' lice

- (c) *List changes to the directions for use:*

None required

- (d) *List changes to the optional marketing claims:*

The following marketing claims must be deleted from the label (pages 4-7)

All references to sandflies, killing/controlling of mites, and 'sucking' lice must be removed from all marketing claims and from the entire label. References to the word 'effective' are deemed inappropriate, as this implies a heightened comparative efficacy claim (a decision on the suitability of this claim is deferred to the product

manager). Finally, any and all claims of 'breaking the flea life cycle' must be deleted, as this product does not kill flea eggs or larvae. On a line-by-line basis, the claims marked with ~~strikethrough-text~~ below must be deleted.

~~"For convenient, quick-acting, long-lasting effective control of fleas ticks . . ."~~

~~" . . (biting, chewing and sucking) lice and mites . . ."~~ All variations of these kill claims must be deleted throughout the label. Claims against mites may be expressed as 'aids in control.'

~~"Kills fleas, ticks, lice, mites and mosquitoes, repels biting flies and mosquitoes"~~

~~"Repels fleas, ticks, biting flies, sandflies and mosquitoes"~~

~~"Research has shown that flea, tick, (sucking, biting, and chewing) lice and mite infestations can be completely controlled with monthly applications of EFFITIX™ Topical Solution for Dogs."~~ The claim 'research has shown' is unacceptable and the claim 'can be completely controlled' implies 100% efficacy, which is also unacceptable.

~~"Effective monthly application against fleas, ticks, and mosquitoes"~~

~~"Fleas: EFFITIX™ Topical solution for dogs can kill adult fleas in 6 hours for up to three months. Apply monthly if your dog . . ."~~

~~"Effective monthly application against fleas"~~

~~"Effective monthly control of fleas"~~

~~"Easy to apply (effective) control . . ."~~

~~"Effectively breaks the flea life cycle"~~

~~"Effective monthly application against ticks"~~

~~"Repels and inhibits blood feeding by biting flies, sandflies and mosquitoes"~~ (delete all other references to sandflies)

~~"Lice: EFFITIX™ Topical Solution for Dogs can kill sucking, biting and chewing lice for . . ."~~ (delete all other references to sucking lice)

~~"Mites: When applied monthly, EFFITIX™ Topical Solution for Dogs kills mites"~~

~~"Mites (Cheyletiella yasguri): When applied monthly . . ."~~

~~"Kills mites (that may cause sarcoptic mange)"~~ Can be revised to 'aids in control of mites that may cause . . .'

~~"Sold by veterinarians"~~

~~"Veterinarian recommended"~~

## SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mail piece or on the front if space permits.

1. Addressee Addressed to:

Timothy (Tim) A. Dotson, Director  
Regulatory Affairs US  
Merial Limited  
3239 Satellite Boulevard, Building  
Duluth, GA 30096-4640

## COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

*I. Gochett*☒ Agent☐ Addressee

B. Received by (Printed Name)

*I. Gochett*

C. Date of Delivery

*8-10-12*D. Is delivery address different from item 1? ☐ YesIf YES, enter delivery address below: ☒ No

3. Service Type

☒ Certified Mail☐ Express Mail☐ Registered☐ Return Receipt for Merchandise☐ Insured Mail☐ C.O.D.

4. Restricted Delivery? (Extra Fee)

☐ Yes

2. Article Number

(Transfer from service label)

7008 3230 0000 9482 3357

PS Form 3811, February 2004

Domestic Return Receipt

102595-02-M-1540

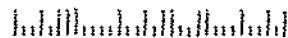
UNITED STATES POSTAL SERVICE



First-Class Mail  
Postage & Fees Paid  
USPS  
Permit No. G-10

• Sender: Please print your name, address, and ZIP+4 in the box •

Mr Richard Gebken (MC 7505P)  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., N.W.  
Washington, CD 20460



**21-Day Screen of Amendment**  
**(Completed by Contractor)**

**21-day Expires on** 3/5/13

**Document Part Of:** 65331-8  
**MRID, If Any:** 490273

**Content Screen: Recommended to**  
**Pass/Fail**

**11-3 Review: Passed/Failed/NA**

**Overall Status: Pass/Fail**

**Document returned to:**

Steve Schaible

1/22 65331-8  
New auto box  
data  
EF

## Memorandum

Date: 1 / 14 / 13

To: PM 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ full
- ☐ par
- ☐ reject

2/11/13  
Steve  
admin/pke  
being expedited  
through OLIS  
SJS  
LV

December 21, 2012



**By Certified Mail**

Bayer Healthcare LLC  
P.O. Box 390  
Shawnee Mission, KS 66201

3239 Satellite Blvd.  
Duluth, GA 30096  
Tel: 678 638 3000

**RE: *Merial Limited Citation of Product Performance Data for EPA Reg. No. 65331-8***

To Whom It May Concern:

Merial Limited, 3239 Satellite Blvd., Building 500, Duluth, GA 30096 is citing MRID 46978901 in support of an efficacy claim for EPA Reg. 65331-8. Merial is citing the data under the selective method of data support. Pursuant to FIFRA §3(c)(1)(F), Merial offers to:

- Pay compensation for data owned by your company (individually or as part of a task force) and submitted to EPA, to the extent required by law, and
- Enter into negotiations to determine which data, if any, may be subject to compensation and the amount and terms of any compensation due.

To the extent that you feel compensation may be due for reliance on data that would support registration of this product, please provide us with the following information so that we may evaluate your claims and commence negotiations:


1. Title of Study;
2. Formulation on which study was conducted (i.e., active ingredient and percent active) and principal inert ingredients (if any);
3. Author (i.e., laboratory conducting the study);
4. Date study was completed;
5. Certification that the study was conducted in accordance with EPA Good Laboratory Practice regulations (40 C.F.R. §160);
6. Certification of access to the raw data;
7. Date study was submitted to EPA;
8. EPA Guideline under which study was submitted to EPA;
9. Proof of EPA's reliance on the study, as indicated in the RED, TRED, or other reregistration correspondence;
10. Proof of EPA's acceptance of the study as Core Guideline, as indicated in the Agency's Data Evaluation Record, or in reregistration correspondence;
11. Actual cost of each item of data, along with an explanation of how each cost figure was derived;
12. Offers to compensate and compensation received to date, by study
13. Relevance of any data claimed to an indoor residential use for pets (dogs).



Page 2  
Dec. 21, 2012

We believe that a mutually satisfactory agreement can be reached governing EPA's use of any data developed by your company on a similar product. If no response is received within thirty (30) days, we will assume that no compensation is requested, and we will proceed accordingly.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. A. Dotson', written over a horizontal line.

Timothy A. Dotson  
Regulatory Affairs US  
Merial Limited  
3239 Satellite Blvd  
Duluth, GA 30096

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 2-12-13 <sup>3/23/09</sup>

Experts In-Processing Signature: P. M. Date 2-12-13 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>65331-8</u>		EPA Receipt Date: <u>2-12-13</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to <a href="http://www.epa.gov/oppr001/inerts/">http://www.epa.gov/oppr001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			x		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )				X	

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			X
	a) List study (or studies) not included with application			

Comments:

MRID 490273 - DATA WAS PREVIOUSLY SUBMITTED, AND  
PASSED H-3 REVIEW. AA 2/12/13

THERE IS NO LABEL INCLUDED IN THE AMENDMENT PACKAGE, AND  
NO PREVIOUSLY SUBMITTED LABEL IS AVAILABLE IN PPLS.

A VOICEMAIL WAS LEFT WITH THE REGISTRANT REGARDING  
THIS ISSUE ON 2/12 AT 9:30 AM. DUE TO THE REQUEST TO  
EXPEDITE, THE JACKET WILL PASS AND BE DELIVERED WITHOUT  
FOLLOW-UP CONTACT WITH THE REGISTRANT. AA 2/12/13

\* EXPEDITED 21-DAY PRA SCREEN REQUESTED \*

\* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is **not** listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 12, 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-475004  
EPA File Symbol or Registration Number: 65331-8  
Product Name: TRADENAME FOR DOGS  
EPA Receipt Date: 26-Dec-2012  
EPA Company Number: 65331  
Company Name: Merial Limited

TIMOTHY A. DOTSON  
Merial Limited  
3239 SATELLITE BLVD.  
DULUTH, GA 30096-4640

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. ...".

Front End Processing Staff  
Information Technology & Resources Management Division

## Fee for Service

{930715"~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

930715

EPA File Symbol/Reg. No.

65331-8

Pin-Punch Date:

12/26/2012

☐ This item is NOT subject to FFS action.

### Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3,617

### Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Stephen A. Schmale

Date: 2/11/13

Remarks:

pkg sent up to PM w/ data initially

PLEASE EXPEDITE THROUGH 21-D PRA SCREEN

# Receipt for Section 3

S: 930715

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 65331 MIERAL LIMITED V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 65331-8 Product Name: TRADENAME FOR DOGS

Overview:

Me Too Section3: Me Too Product Name:

Application Date: 21-Dec-2012

OPP Rec'd Date: 26-Dec-2012

Front End Date: 08-Feb-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Acute toxicity studies and an updated Data Matrix

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

MERIAL LIMITED  
115 Trans Tech Drive  
Athens, GA 30601

Vendor Name ENVIRONMENTAL PROTECTION  
AGENCY

Check Date 20-Dec-2012 Vendor Number 6830

Invoice	Invoice Date	Description	Discount	Net Amount
157165	18-Dec-2012	EPA PRIA Fee	0.00	3,617.00
TOTAL			0.00	3,617.00



\*Commercial/financial information may be entitled to confidential treatment\*



MERIAL LIMITED  
115 Trans Tech Drive  
Athens, GA 30601  
(706) 548-9292

Check Number 571146

Citibank, N.A.  
One Penn's Way  
New Castle DE 19720

62-20  
311

Check Date

20-Dec-2012

Check Amount

\*\*\*\*\*\$3,617.00

Pay Three Thousand Six Hundred Seventeen and 00/100 Dollars\*\*\*\*\*

To The  
or Of ENVIRONMENTAL PROTECTION AGENCY  
US BANK GOVERNMENT LOCKBOX 979074  
1005 CONVENTION PLAZA SL-MO-C2-GL  
ST LOUIS, MO 63197



*James A. Pate*  
AMOUNT OVER \$10,000.00 REQUIRE TWO SIGNATURES



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Merial Limited/65331-8	2. EPA Product Manager Richard Gebkin	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CERTISHIELD for dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code)  Merial Limited 3239 Satellite Blvd., Duluth, GA 30096  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

Submission of new acute toxicity studies for CERTISHIELD and an updated Data Matrix

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Printed	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Timothy A. Dotson		Title Director, RA NPD	
		Telephone No. (Include Area Code) 678-638-3713	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Director, RA NPD	
Typed Name Timothy A. Dotson		5. Date 12/21/12	

**Timothy A. Dotson**  
 Director  
 Regulatory Affairs US  
 Tel: 678-638-3713  
 Fax: 678-638-3715



**3239 Satellite Blvd.**  
**Duluth, GA 30096**  
 Tel: **678 638 3000**

December 21, 2012

Mr. Richard Gebken  
 Registration Division  
 Document Processing Desk  
 Office of Pesticide Programs (7504P)  
 U.S. Environmental Protection Agency  
 Room S-4900, One Potomac Yard  
 2777 South Crystal Drive  
 Arlington, VA 22202

**SUBJECT:** CERTISHIELD™ for dogs, EPA Reg. No. 65331-8  
 Submission of New Acute Toxicity Studies and Updated Data Matrix

Dear Mr. Gebken:

Merial is hereby submitting new acute toxicity studies on the final formulation for CERTISHIELD™ for dogs, EPA Reg. 65331-8, for reevaluation of the labeling precautionary statements. Also, following a phone conversation with Marion Johnson on 18Dec12, we are submitting an alternate Data Matrix which cites data that are not exclusive-use data, and aside from a single study, are non-compensable. We are citing both efficacy and companion animal safety studies, and providing a rationale for "bridging" the individual companion animal safety studies conducted with Frontline (fipronil) and the ones conducted with permethrin. We are also citing Frontline studies for efficacy claims related to fipronil (adulticidal claims), and permethrin studies for efficacy claims relating to permethrin, e.g. repellency. Merial anticipates that any labeling changes required based on the evaluation of the new acute toxicity studies will be undertaken during this review period, with submission of labeling at a later date.

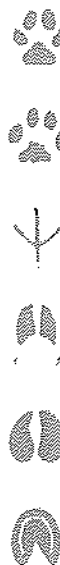
Volume 1 of this submission includes a cover letter, copy of the Application form (8570-1) and PRIA check, Data Certification form, and new Data Matrix. Volume 2 contains the Transmittal Document. Volume 3 contains the justification for bridging fipronil and permethrin studies. Three copies of each final study report are also included.

Merial anticipates that this submission will have PRIA category R340, AMENDMENT REQUIRING DATA REVIEW WITHIN RD (E.G., CHANGES TO PRECAUTIONARY LABEL STATEMENTS). This category provides for a 4-month statutory review time. A fee of \$3,617 is being remitted now in the form of a check payable to the US EPA. A copy of the check is included in this submission.

Thank you for your assistance in this matter. Please call me at 678-638-3713 (email at [Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson  
 Director  
 Regulatory Affairs NP US



## TRANSMITTAL DOCUMENT

**Submitter:** Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640

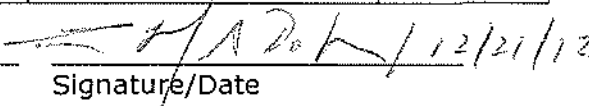
**Regulatory Action:** Submission of new Acute Toxicity studies and an updated Data Matrix for EPA Reg. No. 65331-8

**Transmittal Date:** December 21, 2012

### List of Submitted Volumes:

VOLUME	Guideline	TITLE	MRID NO.
1 of 8	NA	Administrative Materials	
2 of 8	NA	Transmittal Document	
3 of 8	NA	Justification for Bridging Companion Animal Safety and Effectiveness Data for Fipronil and Permethrin	49027301
4 of 8	870.1100	ML-3,141,301: Acute Oral Toxicity Study in the Rat	49027302
5 of 8	870.1200	ML-3,141,301: Primary Dermal Irritation Study in Rabbits	49027303
6 of 8	870.2400	ML-3,141,301: Primary Eye Irritation Study in Rabbits	49027304
7 of 8	870.2500	ML-3,141,301: Acute Dermal Toxicity Study in Rats	49027305
8 of 8	870.2600	Delayed Contact Hypersensitivity in Hartley Guinea Pigs (Buehler Method) with ML-3,141,301	49027306

Company Official: Timothy A. Dotson  
Name

 12/21/12  
Signature/Date

Company Name: Merial Limited

Company Contact: Timothy A. Dotson 678-638-3713  
Name Phone

Email: timothy.dotson@merial.com



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	EPA Registration Number/File Symbol 65331-8
Active Ingredient(s) and/or representative test compound(s) Fipronil + Permethrin	Date December 21, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, non-food use	Product Name CERTISHIELD for dogs

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

Dec. 21, 2012

Timothy A. Dolson, Director

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

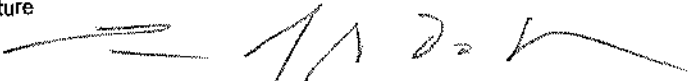
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**DATA MATRIX**

Date December 21, 2012	EPA Reg No./File Symbol 65331-8	Page 1 of 8
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product CERTISHIELD™ for dogs	

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	PRODUCT IDENTITY AND COMPOSITION	48638301	MERIAL	OWN	
830.1600	DESCRIPTION OF MATERIALS USED TO PRODUCE THE PRODUCT	48638302	MERIAL	OWN	
830.1620	DESCRIPTION OF PRODUCTION PROCESS	48638303	MERIAL	OWN	
830.1650	DESCRIPTION OF FORMULATION PROCESS	48638302	MERIAL	OWN	
830.1670	DISCUSSION OF FORMATION OF IMPURITIES	48638301	MERIAL	OWN	
830.1700	PRELIMINARY ANALYSIS	48638303	MERIAL	OWN	
830.1750	CERTIFIED LIMITS	48638301	MERIAL	OWN	
830.1800	ENFORCEMENT ANALYTICAL METHOD	48638303	MERIAL	OWN	
830.1900	SUBMITTAL OF SAMPLES				UPON REQUEST
830.6302	COLOR	ADMIN	MERIAL	OWN	
830.6303	PHYSICAL STATE	ADMIN	MERIAL	OWN	
830.6304	ODOR	ADMIN	MERIAL	OWN	
830.6313	STABILITY TO NORMAL AND ELEVATED TEMP, METALS AND METAL IONS	48638303	MERIAL	OWN	
830.6314	OXIDATION/REDUCTION: CHEMICAL COMPATIBILITY	48638303	MERIAL	OWN	
830.6315	FLAMMABILITY	48638303	MERIAL	OWN	

Signature 	Name and Title Timothy A. Dotson, Director, Reg. Affairs US	Date 12/21/12
--	--	------------------

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

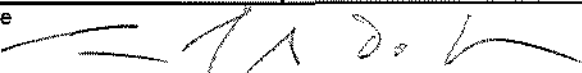
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**DATA MATRIX**

Date December 21, 2012	EPA Reg No./File Symbol 65331-8	Page 2 of 8
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product CERTISHIELD™ for dogs	

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	EXPLODABILITY	48638303	MERIAL	OWN	
830.6317	STORAGE STABILITY	48638303	MERIAL	OWN	
830.6319	MISCIBILITY	48638303	MERIAL	OWN	
830.6320	CORROSION CHARACTERISTICS	48638303	MERIAL	OWN	
830.6321	DIELECTRIC BREAKDOWN VOLTAGE	48638303	MERIAL	OWN	
830.7000	pH	ADMIN	MERIAL	OWN	
830.7050	UV/VISIBLE LIGHT ABSORPTION	48638303	MERIAL	OWN	
830.7100	VISCOSITY	ADMIN	MERIAL	OWN	
830.7200	MELTING POINT/MELTING RANGE	48638303	MERIAL	OWN	
830.7220	BOILING POINT/BOILING RANGE	48638303	MERIAL	OWN	
830.7300	DENSITY/RELATIVE DENSITY/BULK DENSITY	ADMIN	MERIAL	OWN	
830.7370	DISSOCIATION CONSTANTS IN WATER	48638303	MERIAL	OWN	
830.7520	PARTICLE SIZE, FIBER LENGTH, AND DIAMETER DISTRIBUTION	48638303	MERIAL	OWN	
830.7550 830.7560 830.7570	PARTITION COEFFICIENT (n-OCTANOL/WATER)	48638303	MERIAL	DWN	

Signature 	Name and Title Timothy A. Dotson, Director, Reg. Affairs US	Date 12/21/12
--	--	------------------

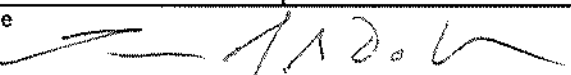
EPA Form 8570-35(9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

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**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 65331-8	Page 3 of 8	
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840 830.7860	WATER SOLUBILITY	48638303	MERIAL	OWN	
830.7950	VAPOR PRESSURE	48638303	MERIAL	OWN	
NOT APPLICABLE	RATIONALE FOR WAIVER REQUESTS	48638303	MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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**DATA MATRIX**

Date December 21, 2012	EPA Reg No./File Symbol 65331-8	Page 4 of 8
Applicant's/Registrant's Name & Address Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product CERTISHIELD™ for dogs	

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE - FLEAS/TICKS	43121114	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS/TICKS	43121115	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43121116	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43121119	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43121120	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43121121	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS/TICKS	43121122	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43444901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43577701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS/TICKS	43577712	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43577713	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	43951701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	44088901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	44942011	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	44942106	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45618501	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45620502	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45620503	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45628104	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45628105	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - FLEAS	45866901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - TICKS	43121117	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - BATHING	43121118	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - SARCOPTIC MANGE	45620504	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - SARCOPTIC MANGE	45620505	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - SARCOPTIC MANGE	45620506	MERIAL	OWN	

Signature

Name and Title

Date

Timothy A. Dotson, Director, Reg. Affairs US

12/21/12

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date December 21, 2012

EPA Reg No./File Symbol 65331-8

Page 5 of 8

Applicant's/Registrant's Name &amp; Address

Product

Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096

CERTISHIELD™ for dogs

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE - MITES	43444901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MITES	43577701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MITES	43951701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MITES	45612701	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MITES	45620503	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MITES	45866901	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - LICE	45620501	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - LICE	45628101	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - LICE	45628102	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - LICE	45628103	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - LICE	45628201	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MOSQUITOES	45866902	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MOSQUITOES	46019202	MERIAL	OWN	
810.3300	PRODUCT PERFORMANCE - MOSQUITOES	46019201	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - FIPRONIL	43863802	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - FIPRONIL	44942104	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - FIPRONIL	45143901	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - FIPRONIL	45620507	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - FIPRONIL	45612702	MERIAL	OWN	
870.7200	COMPANION ANIMAL SAFETY - PERMETHRIN	41056906	COOPER'S ANIMAL HEALTH, INC.	OLD	
870.7200	COMPANION ANIMAL SAFETY - PERMETHRIN	41953201	COOPER'S ANIMAL HEALTH, INC.	OLD	
870.7200	COMPANION ANIMAL SAFETY - PERMETHRIN	43137201	HARTZ MOUNTAIN CORP.	OLD	
870.7200	COMPANION ANIMAL SAFETY - PERMETHRIN	43447101	HARTZ MOUNTAIN CORP.	OLD	
870.7200	COMPANION ANIMAL SAFETY - PERMETHRIN	43396408	ECTO DEVELOPMENT CORP.	OLD	
810.3300	COMPANION ANIMAL SAFETY - PERMETHRIN	43612601	ECTO DEVELOPMENT CORP.	OLD	

Signature

Name and Title

Date

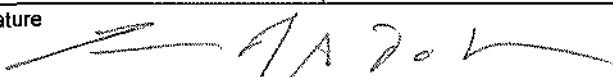
Timothy A. Dotson, Director, Reg. Affairs US

12/21/12

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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 65331-8		Page 6 of 8
Applicant's/Registrant's Name & Address			Product		
Meriat Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	PRODUCT PERFORMANCE	41038803	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43137202	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	41038802	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43137203	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	41683903	COOPER'S ANIMAL HEALTH	OLD	
810.3300	PRODUCT PERFORMANCE	43111607	HARTZ MOUNTAIN CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE - BITING FLY	46978901	BAYER HEALTHCARE L.L.C.	PAY	
810.3300	PRODUCT PERFORMANCE	42256901	COOPER'S ANIMAL HEALTH, INC.	OLD	
810.3300	PRODUCT PERFORMANCE	43396409	ECTO DEVELOPMENT CORPORATION	OLD	
810.3300	PRODUCT PERFORMANCE	43396410	ECTO DEVELOPMENT CORPORATION	OLD	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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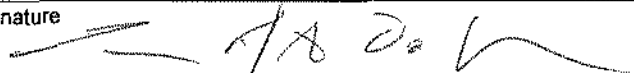
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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date December 21, 2012			EPA Reg No./File Symbol 6533 t-8		Page 7 of 8
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	ACUTE ORAL TOXICITY – RAT	SUBMIT	MERIAL	OWN	
870.1200	ACUTE DERMAL TOXICITY – RAT	SUBMIT	MERIAL	OWN	
870.1300	ACUTE INHALATION TOXICITY				WAIVER
870.2400	PRIMARY EYE IRRITATION – RABBIT	SUBMIT	MERIAL	OWN	
870.2500	PRIMARY DERMAL IRRITATION – RABBIT	SUBMIT	MERIAL	OWN	
870.2600	DERMAL SENSITIZATION – GUINEA PIG	SUBMIT	MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

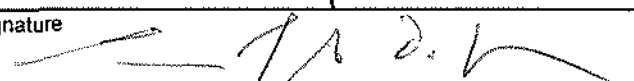
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**DATA MATRIX**

Date December 21, 2012			EPA Reg No./File Symbol 6533t-8	Page 8 of 8	
Applicant's/Registrant's Name & Address			Product		
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096			CERTISHIELD™ for dogs		
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR PART 157, SUBPART B	CR/SAUE TESTING – 6x (XL)	49000901	MERIAL	OWN	
40 CFR PART 157, SUBPART B	CR/SAUE TESTING – 1x (L)	49000902	MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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**DATA MATRIX**

Date December 21, 2012	EPA Reg No./File Symbol 65331-8	Page 1 of 8
Applicant's/Registrant's Name & Address  Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product  CERTISHIELD™ for dogs	

Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
					UPON REQUEST
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	DWN	
Signature 	Name and Title  Timothy A. Dotson, Director, Reg. Affairs US			Date 12/21/12	


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**DATA MATRIX**

Date December 21, 2012		EPA Reg No./File Symbol 65331-8		Page 2 of 8	
Applicant's/Registrant's Name & Address		Product			
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096		CERTISHIELD™ for dogs			
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12

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**DATA MATRIX**

Date December 21, 2012	EPA Reg No./File Symbol 65331-8	Page 3 of 8
Applicant's/Registrant's Name & Address  Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096	Product  CERTISHIELD™ for dogs	


Ingredient Fipronil + Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	

Signature 	Name and Title Timothy A. Dotson, Director, Reg. Affairs US	Date 12/21/12
---	--	------------------

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## DATA MATRIX

Date December 21, 2012		EPA Reg No./File Symbol 65331-8		Page 4 of 8	
Applicant's/Registrant's Name & Address		Product			
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096		CERTISHIELD™ for dogs			
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
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			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
			Signature 		Name and Title
		Timothy A. Ootson, Director, Reg. Affairs US		12/21/12	




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**DATA MATRIX**

Date December 21, 2012		EPA Reg No./File Symbol 65331-8		Page 6 of 8	
Applicant's/Registrant's Name & Address		Product			
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096		CERTISHIELD™ for dogs			
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			COOPER'S ANIMAL HEALTH	OLD	
			HARTZ MOUNTAIN CORPORATION	OLD	
			COOPER'S ANIMAL HEALTH	OLD	
			HARTZ MOUNTAIN CORPORATION	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			COOPER'S ANIMAL HEALTH	OLD	
			HARTZ MOUNTAIN CORPORATION	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			BAYER HEALTHCARE L.L.C.	PAY	
			COOPER'S ANIMAL HEALTH, INC.	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			ECTO DEVELOPMENT CORPORATION	OLD	
			Signature 		Name and Title
		Timothy A. Dotson, Director, Reg. Affairs US		12/21/12	

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Date December 21, 2012		EPA Reg No./File Symbol 6533 t-8		Page 7 of 8	
Applicant's/Registrant's Name & Address		Product			
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096		CERTISHIELD™ for dogs			
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
					WAIVER
			MERIAL	OWN	
			MERIAL	OWN	
			MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/21/12


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**DATA MATRIX**

Date December 21, 2012		EPA Reg No./File Symbol 65331-8		Page 8 of 8	
Applicant's/Registrant's Name & Address		Product			
Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096		CERTISHIELD™ for dogs			
Ingredient Fipronil + Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MERIAL	OWN	
			MERIAL	OWN	
Signature 			Name and Title		Date
			Timothy A. Dotson, Director, Reg. Affairs US		12/24/12

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WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 3, 2012

**Certified Mail: 7008 3230 0000 9482 3340**

Timothy (Tim) A. Dotson, Director  
Regulatory Affairs US  
Merial Limited  
3239 Satellite Boulevard, Building 500  
Duluth, GA 30096-4640

**Subject:** Meeting of June 13 2012, discussing a proposal to self certify another packaging design other than the Frontline Packaging similar to the *FRONTLINE® Plus For Dogs*, EPA Reg. No. 65331-5 which was utilized for purposes of registration of EPA Reg. No. 65331-8.

**Product Name:** Tradename for Dogs

**EPA registration No.:** 65331-8.

Dear Mr. Dotson;

The Agency has reviewed and discussed Merial's Child Resistant Packaging (CRP) self certification proposal presented at the June 13, 2012 meeting at the Office of Pesticide Program's Offices. The Agency cannot accept this proposal, and have determined that additional data will be required per the documentation written by Rosalind Gross (attached). This documentation does not consider any other variant fill weights, or unit packaging than those presented at the June 13, 2012 meeting. Such variants may require additional CRP and/or Companion Animal Safety Studies (CASS) to adequately address the data requirements. When conducting CRP packaging testing, please follow the guidance document attached with this letter. Since **these studies are not part of the conditions of registration**, they must be submitted in accordance with the Pesticide Registration Improvement Act (PRIA), which is part of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA).

Regards,

A handwritten signature in cursive script, reading "Richard J. Gebken".

Richard J. Gebken  
Product Manager PM10  
Office of Pesticide Programs

Attachment: Rosalind Gross memo entitled "EPA Registration Number 65331-8 Additional Data Requirements Per June 13, 2012 Meeting with Merial"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

August 3, 2012

**Certified Mail: 7008 3230 0000 9482 3340**

Timothy (Tim) A. Dotson, Director  
Regulatory Affairs US  
Merial Limited  
3239 Satellite Boulevard, Building 500  
Duluth, GA 30096-4640

**Subject:** Meeting of June 13 2012, discussing a proposal to self certify another packaging design other than the Frontline Packaging similar to the *FRONTLINE® Plus For Dogs*, EPA Reg. No. 65331-5 which was utilized for purposes of registration of EPA Reg. No. 65331-8.

**Product Name:** Tradename for Dogs

**EPA registration No.:** 65331-8.

Dear Mr. Dotson;

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Regards,

Richard J. Gebken  
Product Manager PM10  
Office of Pesticide Programs

Attachment: Rosalind Gross memo entitled "EPA Registration Number 65331-8 Additional Data Requirements Per June 13, 2012 Meeting with Merial"

EPA Registration Number 65331-8  
Additional Data Requirements  
Per June 13, 2012 Meeting with Merial

EPA Registration Number 65331-8 is currently registered as a single pipette (1x) hanging card and a 3x and 6x blister card. The single pipette (1x) is the same shape and style green pipette and hanging card as is used on Frontline Plus EPA Registration Number 65331-5. The 3x and 6x blister card has the same shape and style green pipette and blister packaging as is used on Frontline Plus EPA Registration Number 65331-5.

At a June 13, 2012 meeting Merial indicated they are not currently marketing this package. Merial stated they want to market the product in a 1, 2, 4, and 6 ml filled pipette with a single chamber resembling the two chamber pipette used for EPA Registration Number 65331-7. Furthermore, they want these pipettes to be in the same pouches used for EPA Registration Number 65331-7 and to be sold as a 1x, 3x, and 6x size package. EPA Registration Number 65331-7 pipette sizes are 1.07ml, 2.14ml, 4.28ml, and 6.42ml. It was agreed at the meeting that the differences in the pipette and pouch used for 65331-7 versus the ones to be used for 65331-8 would require additional CRP test data. The test data would need to include at a minimum the following:

- Child-Resistant Effectiveness test for 4ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Senior Adult Effectiveness test for 4ml size pipette filled with water in a single pouch with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Child-Resistant Effectiveness test for 6ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7
- Senior Adult Effectiveness test for 6ml size pipette filled with water as two "three pouch cards" (6x) with the same Senior Adult Effectiveness (SAUE) directions used in testing EPA Registration Number 65331-7

The additional data was conditionally limited to the 4 aforementioned studies, provided the results were not marginal passes per 16 CFR 1700.15(b) and

1700.20. If the results were **marginal passes** per 16 CFR 1700.15(b) and 1700.20 **more testing could be required**. Merial is not marketing the product under its currently approved packaging (resembling Frontline Plus, EPA Registration Number 65331-5). The new packaging (1, 2, 4, and 6 ml filled pipette with a single chamber in a pouch resembling the two chamber pipette and pouch used for EPA Registration Number 65331-7) should be evaluated as a **replacement package not as an additional/alternate package**. This would mean that EPA Registration Number **65331-8 could not be marketed** in a package (resembling Frontline Plus, EPA Registration Number 65331-5).



RE: Completed PRIA Action: Label for 65331-8 (- I -)

Bonaventure Akinlosotu to: Timothy.Dotson

05/15/2012 10:43 AM

Cc: Marion Johnson, Richard Gebken, Kimberly Nesci

History: This message has been replied to.

Please see attached, and respond to acknowledge receipt. Original copy was sent via USPS.



[Untitled].pdf

Thanks, B.A

Thank you for the approval letter. We appreciate...

05/11/2012 02:53:03 PM

From: <Timothy.Dotson@Merial.com>  
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA  
Cc: Richard Gebken/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA  
Date: 05/11/2012 02:53 PM  
Subject: RE: Completed PRIA Action: NOR for 65331-8 (- I -)

Thank you for the approval letter. We appreciate all your help.

Timothy (Tim) A. Dotson  
Director  
Regulatory Affairs US  
Merial Limited  
Ph 678.638.3713  
Cell 404.395.2420  
Fax 678.638.3715

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**From:** Bonaventure Akinlosotu [mailto:Akinlosotu.Bonaventure@epamail.epa.gov]  
**Sent:** Friday, May 11, 2012 1:23 PM  
**To:** Dotson, Timothy AH/US  
**Cc:** Richard Gebken; Marion Johnson  
**Subject:** Completed PRIA Action: NOR for 65331-8 (- I -)

See attached and respond to acknowledge receipt:

(See attached file: [Untitled].pdf)

Please note that the 18 page stamped label (marked up as indicated in NOR) will be sent via USPS.

Thanks, B.A.

---

Bonaventure Akinlosotu, PhD  
Regulatory Scientist  
U.S. Environmental Protection Agency  
Office of Chemical Safety and Pollution Prevention  
OPP/RD (Mail Code: 7505P)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

703-605-0653  
[akinlosotu.bonaventure@epa.gov](mailto:akinlosotu.bonaventure@epa.gov)

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---05/09/2012 09:46:40 AM---Bonaventure, Please find attached the revised label for Tradename for dogs, EPA Reg. 65331-I. The Ma

From: <[Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)>  
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA  
Date: 05/09/2012 09:46 AM  
Subject: EPA Reg No 65331-I; Tradename for Dogs

Bonaventure,

Please find attached the revised label for Tradename for dogs, EPA Reg. 65331-I. The Master text label has been revised to more closely mimic the "me-too" reference product, Effitix Topical Solution for Dogs, EPA Reg. No. 2382-187. The attached Master label (dated 05/09/2012) supersedes the label submitted in the initial application (dated 10/06/11).

Timothy (Tim) A. Dotson  
Director  
Regulatory Affairs US  
Merial Limited  
Ph 678.638.3713  
Cell 404.395.2420  
Fax 678.638.3715

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----- [attachment "Revised  
Final FLARE Master label 09May12 supercedes 06Oct11.docx" deleted by  
Bonaventure Akinlosotu/DC/USEPA/US]



Re: Completed PRIA Action: Label for 65331-8 (- I -)  
Timothy.Dotson  
to:  
Richard Gebken  
05/15/2012 02:05 PM  
Hide Details  
From: <Timothy.Dotson@Merial.com>

To: Richard Gebken/DC/USEPA/US@EPA

History: This message has been replied to.

2 Attachments



graycol.gif 1F176615.gif

Richard,

I'm traveling today and will be back in the office on Thursday. Can I call you then?

Tim

-----  
Sent from my BlackBerry Wireless. Handheld

---

**From:** Richard Gebken <Gebken.Richard@epamail.epa.gov>  
**To:** Dotson, Timothy AH/US  
**Cc:** Bonaventure Akinlosotu <Akinlosotu.Bonaventure@epamail.epa.gov>; Rosalind Gross  
<Gross.Rosalind@epamail.epa.gov>  
**Sent:** Tue May 15 11:13:40 2012  
**Subject:** RE: Completed PRIA Action: Label for 65331-8 (- I -)

Timothy,

Roz brought up what may be an issue with this label that we may need to discuss.  
Has the specific instructions for how to open the package changed from the original testing instructions for the senior testing?  
If so, was this pointed out when the revision was made?

She indicates that the information is different.

Richard Gebken

☞ Bonaventure Akinlosotu---05/15/2012 10:43:27 AM---Please see attached, and respond to acknowledge receipt. Original copy was sent via USPS. Thanks,

From: Bonaventure Akinlosotu/DC/USEPA/US  
To: <Timothy.Dotson@Merial.com>  
Cc: Marion Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA, Kimberly Nesci/DC/USEPA/US@EPA  
Date: 05/15/2012 10:43 AM  
Subject: RE: Completed PRIA Action: Label for 65331-8 (- I -)

---

Please see attached, and respond to acknowledge receipt. Original copy was sent via USPS.

*(See attached file: [Untitled].pdf)*

Thanks, B.A

☞ ---05/11/2012 02:53:03 PM---Thank you for the approval letter. We appreciate all your help. Timothy (Tim) A. Dotson

From: <Timothy.Dotson@Merial.com>  
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA  
Cc: Richard Gebken/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA  
Date: 05/11/2012 02:53 PM  
Subject: RE: Completed PRIA Action: NOR for 65331-8 (- I -)

---

Thank you for the approval letter. We appreciate all your help.

Timothy (Tim) A. Dotson  
Director  
Regulatory Affairs US  
Merial Limited  
Ph 678.638.3713  
Cell 404.395.2420  
Fax 678.638.3715

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**From:** Bonaventure Akinlosotu [mailto:Akinlosotu.Bonaventure@epamail.epa.gov]  
**Sent:** Friday, May 11, 2012 1:23 PM  
**To:** Dotson, Timothy AH/US  
**Cc:** Richard Gebken; Marion Johnson  
**Subject:** Completed PRIA Action: NOR for 65331-8 (- I -)

See attached and respond to acknowledge receipt:

(See attached file: [Untitled].pdf)

Please note that the 18 page stamped label (marked up as indicated in NOR) will be sent via USPS.

Thanks, B.A.

---

Bonaventure Akinlosotu, PhD  
Regulatory Scientist  
U.S. Environmental Protection Agency  
Office of Chemical Safety and Pollution Prevention  
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From: <[Timothy.Dotson@Merial.com](mailto:Timothy.Dotson@Merial.com)>  
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA  
Date: 05/09/2012 09:46 AM  
Subject: EPA Reg No 65331-I; Tradename for Dogs

---

Bonaventure,

Please find attached the revised label for Tradename for dogs, EPA Reg. 65331-I. The Master text label has been revised to more closely mimic the "me-too" reference product, Effitix Topical Solution for Dogs, EPA Reg. No. 2382-187. The attached Master label (dated 05/09/2012) supersedes the label submitted in the initial application (dated 10/06/11).

Timothy (Tim) A. Dotson  
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RE: Completed PRIA Action: Label for 65331-8 (- I -)

Timothy.Dotson

to:

Richard Gebken

05/17/2012 11:44 AM

Cc:

Bonaventure Akinlosotu, Rosalind Gross

Hide Details

From: <Timothy.Dotson@Merial.com>

To: Richard Gebken/DC/USEPA/US@EPA

Cc: Bonaventure Akinlosotu/DC/USEPA/US@EPA, Rosalind Gross/DC/USEPA/US@EPA

3 Attachments



image001.gif image002.gif Revised Final FLARE Master label 17May12 supercedes 06Oct11 TC.docx

Richard,

I believe I found the inconsistency for instructions for opening the single-dose pipette and have corrected it. Also, I'm providing comments in track changes for your consideration. Once we have agreement I will send you a "clean" copy.

Timothy (Tim) A. Dotson  
Director  
Regulatory Affairs US  
Merial Limited  
Ph 678.638.3713  
Cell 404.395.2420  
Fax 678.638.3715

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**From:** Richard Gebken [mailto:Gebken.Richard@epamail.epa.gov]  
**Sent:** Tuesday, May 15, 2012 11:14 AM  
**To:** Dotson, Timothy AH/US  
**Cc:** Bonaventure Akinlosotu; Rosalind Gross  
**Subject:** RE: Completed PRIA Action: Label for 6S331-8 (- I -)

Timothy,

Roz brought up what may be an issue with this label that we may need to discuss.  
Has the specific instructions for how to open the package changed from the original testing instructions for the senior testing?  
If so, was this pointed out when the revision was made?

She indicates that the information is different.

Richard Gebken

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From: Bonaventure Akinlosotu/OC/USEPA/US  
To: <Timothy.Dotson@Merial.com>  
Cc: Marlon Johnson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA, Kimberly Nesci/OC/USEPA/US@EPA  
Date: 05/15/2012 10:43 AM  
Subject: RE: Completed PRIA Action: Label for 65331-8 (- I -)

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Please see attached, and respond to acknowledge receipt. Original copy was sent via USPS.

*(See attached file: [Untitled].pdf)*

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From: <Timothy.Dotson@Merial.com>  
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA  
Cc: Richard Gebken/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA  
Date: 05/11/2012 02:53 PM  
Subject: RE: Completed PRIA Action: NOR for 65331-8 (- I -)

---

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**From:** Bonaventure Akinlosotu [mailto:Akinlosotu.Bonaventure@epamail.epa.gov]

**Sent:** Friday, May 11, 2012 1:23 PM

**To:** Dotson, Timothy AH/US

**Cc:** Richard Gebken; Marion Johnson

**Subject:** Completed PRIA Action: NOR for 65331-B (- I -)

See attached and respond to acknowledge receipt:

(See attached file: [Untitled].pdf)

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Thanks, B.A.

---

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U.S. Environmental Protection Agency  
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